



**ASSESSMENT
OF THE
CONTRACEPTIVE TECHNOLOGY RESEARCH PROJECT
AT
FAMILY HEALTH INTERNATIONAL
1995–2005**

**Claudia Morrissey Conlon
Gordon Duncan
Noel McIntosh
Julie Solo**

October 2003

**Submitted by:
LTG Associates, Inc.
TvT Global Health and Development Strategies™
a division of Social & Scientific Systems, Inc.**

**Submitted to:
The United States Agency for International Development
Under USAID Contract No. HRN-C-00-00-00007-00**

This document is available in printed or online versions (POPTECH Publication Number 2003–127–018). To review and/or obtain a document online, see the POPTECH web site at www.poptechproject.com. Documents are also available through the Development Experience Clearinghouse (www.dec.org). Additional information about this and other POPTECH publications may be obtained from

The Population Technical Assistance Project
1101 Vermont Avenue, NW, Suite 900
Washington, DC 20005
Telephone: (202) 898-9040
Fax: (202) 898-9057
admin@poptechproject.com

Assessment of the Contraceptive Technology Research Project at Family Health International was made possible through support provided by the United States Agency for International Development (USAID) under the terms of Contract Number HRN–C–00–00–00007–00, POPTECH Assignment Number 2003–127. The opinions expressed herein are those of the authors and do not necessarily reflect the views of USAID.

ACKNOWLEDGMENTS

This assessment could not have been conducted without the help and support of a large number of people in Kenya, North Carolina, and Washington, DC. The assessment team wishes to express special appreciation to the staff and leadership of the Contraceptive Technology Research (CTR) project, Family Health International headquarters in Research Triangle Park, North Carolina, and CTR/Nairobi East and Southern Africa (ESA) Regional Office. At both sites, senior staff members were eager to engage the team in productive discussions that greatly enhanced the team's understanding of the CTR project and richly contributed to the writing of the report. In particular, the team wishes to thank JoAnn Lewis, senior vice president, Institute of Family Health, as well as Ndugga Maggwa, director, and Maureen Kuyoh, deputy director, of the CTR/Nairobi ESA Regional Office.

The team wishes to acknowledge the support of the Bureau for Global Health, U. S. Agency for International Development (USAID), Washington, D.C., especially the staff of the Research, Technology and Utilization Division, who developed an outstanding scope of work and helped prepare the team in many ways to undertake the assessment. In particular, the team expresses special thanks to Jeffrey Spieler, division chief, and Mihira Karra, technical advisor, for their encouragement, guidance, and support. The team also wishes to thank USAID Mission staff members from Ethiopia, Madagascar, South Africa, and Uganda, who were interviewed by telephone, and Michael Strong and Sheila Macharia of USAID/Kenya, with whom the team met in Nairobi, for their cogent comments and suggestions.

The team extends its appreciation to Melanie Kindsfather and David Barnettler of the Population Technical Assistance Project (POPTECH). Among the many things they did to make the work of the team easier was to schedule more than 50 telephone interviews around the world.

ACRONYMS AND ABBREVIATIONS

BASS	Behavioral and Social Sciences Research Group (FHI)
BCC	Behavior change communication
CA	Cooperating agency
CBR	Center for Biomedical Research (the Population Council)
CDC	Centers for Disease Control and Prevention
CEO	Chief executive officer
CICCR	Consortium for Industrial Collaboration in Contraceptive Research (CONRAD)
CONRAD	Contraceptive Research and Development Program
CRD	Clinical Research Department (FHI)
CTO	Cognizant technical officer (USAID)
CTR	Contraceptive Technology Research project (FHI)
CTR/Nairobi	CTR East and Southern Africa Regional Office (FHI)
ECPG	Essential Care Practice Guidelines
ESA	East and Southern Africa
FDA	U.S. Food and Drug Administration (U.S. Department of Health and Human Services)
FHI	Family Health International
FITS	Field Information and Training Services Department (FHI)
FP	Family planning
GH/HIDN	Bureau for Global Health, Office of Health, Infectious Diseases and Nutrition
GH/OHA	Bureau for Global Health, Office of HIV/AIDS
GH/PRH	Bureau for Global Health, Office of Population and Reproductive Health
GH/PRH/CSL	Bureau for Global Health, Office of Population and Reproductive Health, Commodities Security and Logistics Division
GH/PRH/RTU	Bureau for Global Health, Office of Population and Reproductive Health, Research, Training and Utilization Division
GH/PRH/SDI	Bureau for Global Health, Office of Population and Reproductive Health, Service Delivery Improvement Division
GMP	Global Microbicide Project (CONRAD)
GRIPP	Getting Research into Policy and Practice Initiative
GTZ	German Technical Cooperation
HIV/AIDS	Human immunodeficiency virus/acquired immune deficiency syndrome
HPTN	HIV Prevention Trials Network
HSR	Health Services Research Division (FHI)
IBP	Implementing Best Practices Initiative
ICPD	International Conference on Population and Development (Cairo)
IFH	Institute for Family Health (FHI)
IMPACT	Implementing AIDS Prevention and Care project (FHI)
IPM	International Partnership for Microbicides
IR	Intermediate Result
IUD	Intrauterine device
MAQ	Maximizing Access and Quality Initiative
MOH	Ministry of Health
MTCT	Mother-to-child transmission
NDA	New drug application
NGO	Nongovernmental organization
NICHD	National Institute of Child Health and Human Development
NIH	National Institutes of Health
OR	Operations research
PATH	Program for Appropriate Technology in Health
PHSC	Protection of Human Subjects Committee (FHI)

PMA	Premarket approval application
PMTCT	Prevention of mother-to-child transmission
POPTECH	Population Technical Assistance Project
PQC	Product Quality and Compliance Group (FHI)
QC/QA	Quality control/quality assurance
QSD	Quantitative Sciences Department (FHI)
R&D	Research and development
RH	Reproductive health
RHD	Reproductive Health Programs Department (FHI)
RtoP	Research to Practice Initiative
STI	Sexually transmitted infection
TAC	Technical advisory committee
TRIP	Turning Research into Practice Initiative
USAID	U. S. Agency for International Development
VCT	Voluntary counseling and testing
WHO	World Health Organization
WHO/RHR	World Health Organization, Department of Reproductive Health and Research

CONTENTS

	Page
Executive Summary	i
I. Introduction.....	1
Background	1
Methodology	1
II. Findings and Recommendations	4
Strengths and Weaknesses	4
Strengths	4
Weaknesses	5
Research Quality and Impact	7
Overview	7
Contraceptive and Microbicide Research	9
Behavioral, Economic, and Programmatic Research.....	10
Research to Practice	12
Product Quality and Compliance Group	14
Management and Financial Issues	15
Strategic Planning and Coordination	15
Role of CTR Within the New Institute for Family Health.....	16
Role of the CTR Technical Advisory Committee.....	17
CTR East and Southern Africa Regional Office (CTR/Nairobi) and Staff Needs	17
Resource Allocation To Maximize Efficiency and Effectiveness	18
Portfolio Assessment	20
Contraceptive and Microbicide Research Relative to CONRAD and the Population Council.....	20
Program Research Relative to FRONTIERS and Other Operations Research...	24
III. Future Directions	26
Introduction.....	26
Proposed Configuration	26
Contraceptive and Microbicide Research.....	29
Role of the CTR Project.....	29
Issues With the Proposed Clinical Trials	30
Role of USAID.....	32
Product Quality and Compliance	32
Behavioral, Economic, and Programmatic Research.....	33
Capacity Building	34
Staff Development	35
Study Site Identification and Development	36
Research to Practice	37
Monitoring and Evaluation	38
Funding Mechanisms	39

TABLES

1. Outputs for Measurement of CTR Success.....	8
2. Highlights of CTR Research and Use in Kenya	12
3. IFH Departments and Functions	17

FIGURE

Microbicides Research: A Comprehensive Approach.....	27
--	----

APPENDICES

- A. Scope of Work
- B. Persons Contacted
- C. Kenya Trip Report
- D. References

EXECUTIVE SUMMARY

BACKGROUND

The current cooperative agreement between the U. S. Agency for International Development (USAID) and Family Health International (FHI) was awarded in 1995 and ends August 30, 2005. The Contraceptive Technology Research (CTR) project is intended to support research and development (R&D) of new or improved contraceptive and microbicidal products that are effective, safe, acceptable, and affordable, and that can be provided through family planning (FP), HIV prevention, and other reproductive health (RH) programs in developing countries. In part because of USAID's continuous, consistent, and long-term investment in the CTR project over nearly three decades, FHI has become the leading public sector biomedical and biotechnical research organization.

METHODOLOGY

The purpose of this assessment was to

- assess the performance of the CTR project relative to the goals and objectives of the cooperative agreement,
- assess the results of CTR's research findings and capacity-building activities on FP and RH programs worldwide, and
- provide guidance to USAID for the design of a follow-on project.

A team of four individuals conducted the assessment over a 6-week period from mid-September through October 2003. Sources of information included

- background documents, including a comprehensive self-assessment prepared by FHI;
- interviews with over 70 individuals from 23 different organizations;
- discussions with staff from USAID/Washington and five Missions;
- meeting with FHI/CTR staff in North Carolina for 3 days; and
- a week-long visit to Kenya to meet with CTR/Nairobi East and Southern Africa (ESA) Regional Office staff and to make field visits to ongoing research studies.

KEY FINDINGS AND RECOMMENDATIONS

Strengths

“FHI is uniquely positioned to do a lot of good for the world.”

CTR received high marks for its clinical R&D capacity. Respondents also complimented CTR staff members for being collaborative, characterizing them as “highly skilled,” “forward thinking,” “flexible,” and “very technically competent professionals who are passionate about the work they do.” Many individuals praised CTR for providing leadership in the integration of FP and HIV/AIDS and male and female condom use as well as for advocating an RH focus in the face of vertical HIV/AIDS funding.

Weaknesses

“They need to be more intellectually proactive and strategic rather than just responsive.”

Several respondents commented that CTR has largely followed the direction of USAID/Washington, that it is too headquarters based, and that “they need to make more strategic decisions on which studies to undertake.” Respondents also raised several management issues as weaknesses, including the need to decentralize decision-making. Finally, although many respondents spoke positively about FHI’s efforts to disseminate research findings, most acknowledged that taking research to practice is a challenge for all research organizations.

Research Quality and Impact

Since 1971, CTR has had an integral role in helping USAID achieve its contraceptive research goals and objectives. In the past eight years, CTR has either met or exceeded all of the output targets set as the evaluation criteria in the cooperative agreement. CTR completed 137 studies to understand and improve contraceptive method use (50 were projected), conducted 6 phase 2/3 safety and efficacy clinical trials (3 were projected), and introduced new methods into 11 countries (5 were projected). CTR should be commended for this success. This measurement, however, stops short of showing impact in terms of programmatic change and putting research into practice. **Addressing this gap should be encouraged and measured in the follow-on project.**¹

Contraceptive and Microbicide Research

In the current CTR agreement, 150 studies were conducted to evaluate contraceptive safety and efficacy, assess contraceptive risks and benefits, and improve contraceptive method use. These studies led to the approval of five contraceptive products by the U. S. Food and Drug Administration (FDA) (the Filshie Clip, eZon condom, Tactylon condoms, FemCap, and the Lea’s contraceptive device). Other studies led USAID to discontinue providing vaginal foaming tablets and to cease recommending use of nonoxynol-9 as a spermicide. In addition to the six phase 2/3 safety and efficacy studies with condoms, diaphragms, spermicides, vaginal gels, and vasectomy technologies, CTR has three phase 2/3 studies with microbicides in progress.

Behavioral, Economic, and Programmatic Research

CTR undertakes both health services research and behavioral and social sciences research. A significant proportion of ongoing CTR studies (39 percent) are taking place in FHI’s East and Southern Africa (ESA) Region, with most of the studies being

¹ Throughout the report, recommendations by the assessment team are shown in boldface type.

conducted in Kenya. CTR's research in Kenya has led to a number of changes in policies and programs in the country. For example, a study on menstruation requirements as a barrier to contraceptive access led to the development of a checklist to rule out pregnancy and thereby increased access to contraception for nonmenstruating women. ***The important question now is how CTR can achieve a similar impact in countries where it does not have the same level of field staff or Mission support.***

Research to Practice Initiative

With the creation of the Research to Practice (RtoP) Initiative in 2001, CTR introduced a more formalized approach to turning research into practice and has begun to change the organizational culture of FHI to institutionalize a research to practice approach. The RtoP Initiative has focused primarily on identifying key priorities among existing CTR findings to bring into practice. Using three criteria—a solid body of evidence, public health impact, and likelihood of use—staff identified four key priorities: intrauterine devices (IUDs), checklists, vasectomy, and nonoxynol-9 spermicides. ***In the future, it would be useful to explicitly apply a similar but modified set of criteria when choosing to undertake studies.*** One of the first major activities of the RtoP Initiative has been to reintroduce the IUD in Kenya. ***The lessons from this experience should be used to help inform future research to practice efforts.*** Field presence greatly enhances turning research into practice because “locally based staff have the best understanding of issues.” Therefore, **CTR should examine ways to take advantage of the global presence of FHI's Implementing AIDS Prevention and Care (IMPACT) Project**, which has field offices in more than 40 countries.

Product Quality and Compliance Group

The Product Quality and Compliance Group (PQC) is one of a few laboratories in the world capable of performing high-quality condom testing. Over the years, PQC has provided technical assistance in the areas of quality assurance, product evaluation, standards development, training on standards, and enhancement of laboratory capacities. This is reflected in the continued requirement for PQC to retest 100 percent of all lots.

Management and Financial Issues

In recent years, the magnitude and rate of growth at FHI accelerated to the point that major restructuring was required. Over the past two years, FHI has been split into two parallel institutes, HIV/AIDS and Family Health; each is headed by a president and a chief operating officer (senior vice president for operations, a new position created to relieve each president of many day-to-day management and administrative duties). Because of CTR's increasing involvement in HIV/AIDS research and programs, **these two institutes should work more closely in developing their work plans to take advantage of potential synergies.**

Portfolio Assessment

Contraceptive and Microbicide Research Relative to the Contraceptive Research and Development Program (CONRAD) and the Population Council

The contraceptive and microbicide programs at CONRAD, the Population Council (the Center for Biomedical Research [CBR]), and FHI (CTR), which are supported by USAID cooperative agreements, are supplementary and complementary. USAID's support of these three organizations provides a greater opportunity for success in USAID's mission to develop new and improved contraceptives and microbicides. In addition, continuing support of these agencies is more important now than ever before because these two areas of research—contraceptives and microbicides—have become critically dependent on public sector support due to the exodus or lack of interest of industry. **USAID should continue to support CTR, CONRAD, and the Population Council's CBR in their critical R&D efforts to provide the public with new or improved contraceptives and microbicides.**

Program Research Relative to FRONTIERS and Other Operations Research

Although multiple USAID-funded organizations engage in operations research (OR), the two primary agencies involved in OR are FHI, through its Health Services Research Group (HSR), and the Population Council, through FRONTIERS and Horizons. CTR conducts programmatic research on contraceptive technology, which is driven by family planning methods. For the FRONTIERS project, the focus is more on systems; its OR generally “does not start with a method, but looks at the situation of program managers.” In addition to the fact that there is little overlap between the CTR and FRONTIERS portfolios, there are also many benefits to having multiple organizations involved in OR, including increased innovation and creativity. **USAID should continue to support the OR programs of both CTR and FRONTIERS.**

FUTURE DIRECTIONS

The current CTR agreement began in August 1995, one year after the pivotal International Conference on Population and Development (ICPD) in Cairo. ICPD helped to expand the perspective of the population and FP field to look more broadly at RH. Now, almost 10 years later, FP is at risk of being lost due to the dominance of HIV/AIDS in public thinking and donor funding. With 230 million women in the world lacking information on and access to a full range of contraceptive methods, it is essential not to lose focus on the unfinished FP agenda. Towards that end,

- **USAID should ensure continued high levels of funding for FP and**
- **CTR should ensure a continuing focus on improving FP programs.**

Proposed Configuration

Initially focused on carrying out clinical trials of contraceptive methods, CTR has grown to embrace behavioral, programmatic, and economic research and to create methodologies and high standards for how this research should be conducted in the developing world. CTR also ensures the quality of condoms and other family planning methods through PQC. Respondents were unanimous in their support for maintaining

CTR's broad capabilities in a future project: "I think this [CTR] has worked—USAID needs to think carefully before they dissect it." **The follow-on CTR agreement should maintain the same components and capabilities—clinical, behavioral, economic, and programmatic research; product quality testing; and the research to practice approach—found in the present project.**

Contraceptive and Microbicide Research

Because the contraceptive pipeline is not very robust, the focus of a follow-on project should be to make existing methods more attractive and widely used. While it is important to remain prepared to undertake phase 2 and 3 evaluations of any contraceptive candidates that emerge from CONRAD's pipeline, **CTR needs to remain focused on research to extend the safety and acceptance of existing contraceptives and to improve their continuation rates.**

There is an urgent public health need to develop a woman-controlled vaginal microbicide to reduce the transmission of HIV/AIDS during intercourse. There is concern, however, regarding the large-scale study design of the proposed (and soon to be ongoing) phase 2 and 3 clinical trials of up to eight compounds. The failure to perform phase 2 studies to assess efficacy using a small number of subjects is a major constraint to the selection and/or establishing the priority of the microbicide candidates as well as dosage and treatment regimens. **USAID and CTR should continue to press for simpler, less expensive study designs (e.g., two-arm, fewer subjects) and take the lead in working with collaborators to implement a strategy for selecting and setting priorities for those microbicides in various pipelines.** Despite these concerns, however, **CTR should continue as quickly as possible the assessment of Savvy and cellulose acetate as well as any other microbicides that CONRAD may offer for clinical testing.** The conservative, streamlined clinical trial design proposed by CTR should be used, while remaining vigilant for potential improvements.

Product Quality and Compliance Group

Although it would be possible to establish a freestanding organization with the same or similar mission as PQC, both CTR and PQC benefit from their integrated association. Separation of PQC from CTR would provide neither economies of nor efficiencies in their operations. **PQC should remain a component of FHI with an expanded scope of work and its mission should be included as an integral part of CTR in the follow-on project.**

Behavioral, Economic, and Programmatic Research

The two key priority areas for future behavioral, economic, and programmatic research are

- *increasing the use and continuation rates of existing FP methods.* As one respondent asked, "Have we gotten all the mileage out of what's out there already?"
- *understanding the integration and interaction of FP and HIV/AIDS.* This includes exploring contraception/HIV health considerations and improving the

integration of FP and HIV/AIDS, for example, through voluntary counseling and testing (VCT) and prevention of mother-to-child transmission (PMTCT) services.

Capacity Building

Having a sufficient number of qualified researchers and clinical trial sites is critical over the next 10–15 years (at a minimum) for winning the war against AIDS, tuberculosis, and malaria, and to continuing contraceptive research. **CTR should continue to build on its comparative advantage by focusing on increasing the number of developing country researchers and local staff qualified to design, implement, analyze, and use the results of contraceptive and microbicide research, and by identifying and developing clinical trial sites.**

Research to Practice

Although in its infancy, the RtoP Initiative is a necessary addition to CTR’s portfolio. ***CTR should continue an RtoP Initiative, and a discrete amount of core funds should be set aside for this activity.*** In addition, several respondents stated that “this type of initiative is critical but should be bureauwide and involve all the cooperating agencies (CAs).” **USAID should consider creating a new procurement that would expressly facilitate the use of best practices.**

Monitoring and Evaluation

The current CTR agreement has focused on output measurements, such as number of studies conducted, number of peer-reviewed publications, and number of workshops. With the current focus and attention placed on turning research into practice, it is important that the follow-on project contain more emphasis than the current project on outcome and effectiveness measures. This will help to ensure that the next CTR agreement is guided by the principles of turning research into practice. In addition, documenting, measuring, and analyzing the research and use process will provide valuable insights and lessons on how better to translate research into practice and impact. For the next project, **staff from FHI, the Population Council, and USAID’s Research and Technology Utilization (RTU) and Service Delivery Improvement (SDI) divisions should develop a core set of indicators for measuring both the determinants and extent of use of research findings.**

Funding Mechanisms

The follow-on project should continue as a cooperative agreement, allowing flexibility in interpretation and implementation with substantial involvement by USAID/Washington. **The present level of core funding should be maintained or increased for the follow-on project.** By all accounts, it may take more than a decade for the microbicide research currently in the pipeline (even if rationalized to a few of the best leads) to result in highly effective products. Dismantling the existing research infrastructure in the current CTR—and thus derailing further development and introduction of these products—would set the public health agenda back by a decade. **USAID should continue its support of current CTR contraceptive and microbicide research by awarding a 10-year,**

noncompetitively bid cooperative agreement to FHI when the present project ends in 2005.

In summary, by benefiting from nearly three decades of CTR funding, FHI has become one of only a few organizations that has the breadth and expertise to conduct high-quality RH research in the developing world. Many of those interviewed expressed support for continuing to infuse this RH capacity and perspective into HIV/AIDS programs and research. In order to continue to promote this approach, **the follow-on CTR agreement should broaden its research mandate to allow for funding and research requests from the three offices in USAID's Bureau for Global Health—Population and Reproductive Health (GH/PRH), HIV/AIDS (GH/OHA), and Health, Infectious Diseases and Nutrition (GH/HIDN).** Such a funding mechanism would allow CTR to bring its contraceptive research (clinical, behavioral, programmatic, and economic) and RH focus to bear on the current major public health problems and to promote integrated solutions to complex problems.

I. INTRODUCTION

BACKGROUND

The Contraceptive Technology Research (CTR) project is a cooperative agreement between the U. S. Agency for International Development (USAID) and Family Health International (FHI). The overall goal of the project is to increase the means available to couples in developing country to achieve their desired family size. The specific objectives are to develop and introduce a range of safe, effective, and acceptable methods of family planning, and more recently, disease prevention technologies; to strengthen the capacity of developing country researchers; and to improve provider practices. The CTR agreement was awarded in 1995 and ends August 30, 2005. The current award is a continuation of two previous 10-year cooperative agreements given to FHI and is supported and managed by the Research, Technology and Utilization Division of the Bureau for Global Health, Office of Population and Reproductive Health (GH/PRH/RTU).

Since 1971, CTR project staff members have carried out a program of research, technical assistance, and information dissemination of new or improved contraceptive products that are effective, safe, acceptable, and affordable. These products, when approved, can be provided through family planning (FP) and other reproductive health (RH) programs that serve the needs of developing countries. In the current cooperative agreement, CTR, at the request of USAID, has emphasized the development and testing of new barrier methods—both physical and chemical (e.g., microbicides)—for prevention of HIV transmission and pregnancy. In addition, CTR has supported a large volume of social and behavioral research, expanded its information dissemination capability, and continued to provide high-quality testing and surveillance of contraceptive commodities used in USAID-supported RH programs throughout the world.

The purpose of this assignment was to

- assess the performance of the CTR project relative to the goals and objectives of the cooperative agreement,
- assess the results of CTR's research findings and capacity-building activities on family planning and reproductive health programs worldwide, and
- provide guidance to USAID for the design of a follow-on project.

In conducting the assignment, the assessment team was instructed to spend half its efforts on assessing performance and results and half on providing guidance and direction for a follow-on project. (See appendix A for the complete scope of work.)

METHODOLOGY

The assessment team consisted of four individuals with expertise in contraceptive, microbial, behavioral, social science, and HIV prevention technologies and research as well as experience in the development, implementation, and evaluation of international research and RH service delivery programs. Before conducting site visits to FHI's

headquarters in North Carolina (3 days) and the regional office in Kenya (7 days), the team first reviewed a number of documents that detailed the performance and results of CTR activities, and was then briefed by members of the RTU Division at USAID. The team also met with 16 staff members from USAID's Commodities Security and Logistics (GH/PRH/CSL) and Service Delivery Improvement (GH/PRH/SDI) divisions and spoke with USAID Mission staff from Ethiopia, Kenya, Madagascar, South Africa, and Uganda during the course of the assignment.

Of the documents reviewed, the most important included the CTR cooperative agreement (1995) and the most recent external evaluation report (1994); two annual reports and work plans (2002–03 and 2003–04); the two most recent management reviews (2001 and 2002); an interim report (2002); the agenda, PowerPoint presentations, materials, and draft minutes from the May 2003 meeting of the Technical Advisory Committee (TAC); and major publications produced under CTR. These included the following:

- *Latex Condom* (a monograph),
- *Qualitative Research Methods* (a manual),
- *Research Ethics Training Curriculum*,
- *Meeting the Needs of Young Clients* (a monograph), and
- 14 back issues of *Network* (1997–2003), including the latest issue devoted to the Research to Practice (RtoP) Initiative.

In addition, FHI prepared a detailed self-assessment that covered the key areas of interest and concern to USAID/Washington. This self-assessment was particularly helpful in understanding the role CTR has played in furthering USAID's contraceptive and microbicide research and development agenda. (Key information and findings in the self-assessment are referred to throughout the report, with FHI's permission.) During the course of the assignment, more than 70 non-FHI affiliated stakeholders (i.e., staff and faculty from 23 agencies, organizations, and universities) were interviewed by telephone using a questionnaire based on the specific questions to be addressed by the team as detailed in the scope of work.² Frank, open, and knowledgeable exchanges characterized these interviews and meetings. (See appendix B for the list of persons contacted.)

As an initial step, the team selected its focus areas from a matrix of key questions included in the scope of work. These questions were based on the cooperative agreement's strategic framework and issues of interest and concern to USAID. In particular, USAID/Washington wished to know the answers to the following questions:

1. How well do the various parts of FHI interact and function to implement the CTR project? Is there a continued need for all of them in the design of a follow-on project?

² The comments from those interviewed were collated by category and ranked using a semi-quantitative process. The team incorporated the most relevant comments into the text of the report as direct quotations. In this way, the specific comments of the respondents convey the flavor of the fieldwork, although their inclusion does not follow POPTECH's editing conventions.

2. What are the merits of expanding the role of information dissemination through the new RtoP Initiative as a mechanism to increase utilization of key research results?
3. What are the best ways to facilitate the process of transferring key research findings and best practices into country programs, not only for a future follow-on project but also for USAID across all its cooperating agencies (CAs) and contractors?

II. FINDINGS AND RECOMMENDATIONS

STRENGTHS AND WEAKNESSES

More than 70 interviews were conducted with non-FHI affiliated stakeholders who could assess the general performance of CTR and/or inform the team regarding the design of a follow-on USAID procurement. All interviewees were first asked about the general strengths and weaknesses of the CTR project. The responses noted below represent major themes that emerged from this question.

Strengths

“FHI is uniquely positioned to do a lot of good for the world.”

Clinical Studies

Without exception, those interviewed gave high marks to the project’s clinical research and development capacity. Phrases such as “highest quality,” “most respected,” “great reputation,” and “internationally recognized” were common. Those questioned stated that FHI has the ability to perform the necessary clinical studies for microbicides, and that it “is one of only two organizations that can conduct these kinds of large, phase 3 clinical trials.” FHI’s long history of successful research efforts has contributed significantly to improving the safety and efficacy of contraceptive methods. Respondents believe that CTR can quickly set up and undertake field studies given its in-house talent and standard operating procedures and that it is poised to do the same for microbicides.

CTR Staff

Respondents characterize CTR staff as being “highly skilled, forward thinking, and flexible.” The biostatistics staff was frequently singled out for praise because of its excellent analytical capabilities and collegiality. Perhaps because of its easy to use services, several respondents deemed the biostatistics group to be understaffed and “stretched too thin.” Most respondents stated that CTR staff members are eager to collaborate. One noted that CTR is a “super organization to work with,” while another stated that CTR staff “look for creative ways to work together. Commitment to users was also mentioned. As one respondent stated, “FHI staff are very technically competent professionals who are passionate about the work they [FHI] do for disadvantaged populations.”

Partnerships

Those questioned stated that CTR has been able to forge good relationships with government counterparts while conducting research in the field. CTR is “very responsive to Missions and field needs” and shows “enormous patience” in its collaborations with local research organizations. “They’re trusted, reliable partners.” FHI has also been accommodating to USAID’s changing program needs. Over the years, “FHI and USAID have established a relationship built on trust and benefiting from continuity.” FHI’s long history of public sector orientation with the delivery of useful information has created confidence in the quality and impact in its work “as shown in consistent and growing funds from [Mission] field support.”

Leadership

Beyond conducting current and proposed clinical trials of international import, CTR has an experienced sense of RH research in Africa. Many of those interviewed praised CTR for providing leadership in the integration of contraception and HIV/AIDS, male and female condom use, reintroduction of the IUD, and the relationship between hormonal contraception and acquisition of HIV. “They are always at the table when important issues are being discussed, always vocal, and they are a voice that comes with evidence.” “The CTR team takes a very concrete approach to problems in the real world; helps us rationalize the efforts we undertake.” “Their research is believable.”

Reproductive Health Focus

FHI is also seen as an advocate for maintaining an RH focus in the face of vertical HIV/AIDS funding. “FHI fills an important need by keeping an RH perspective in microbicide work and looking holistically at women’s needs.” The CTR/Nairobi Regional Office was credited with helping to bring together the HIV/AIDS and reproductive health offices at the Kenyan Ministry of Health (MOH) by supporting research that integrated HIV/AIDS and FP within an RH framework.

Research to Practice

Many respondents spoke positively about FHI’s efforts to disseminate research findings, although most acknowledged that taking research to practice is a challenge for all research organizations. “They do not just walk away when research is completed. FHI is good at getting research results out to the research community through publications, presentations, and press releases.”

Product Quality Assurance

Those interviewed with expertise in product quality and safety were uniformly laudatory of the work performed by the Product Quality and Compliance (PQC) unit, describing them as “responsive,” “collaborative,” and “among the best in the world.” One USAID staff person stated, “When problems arise you can call PQC, and they’ll go to the field, pull and test samples, and advise. We get more than just testing; we are partners.” Several commended PQC for recruiting members to its TAC that would be critical and provide good insight into contraceptive quality testing.

Weaknesses

“They need to be more intellectually proactive and strategic rather than just responsive.”

Strategic Focus

Several respondents commented that CTR has not been sufficiently strategic or innovative when developing its research portfolio, even though USAID has provided good strategic guidance. (FHI acknowledges this issue as well in the self-assessment.) Given the level of expertise and experience resident in the project, it was noted that increased global leadership is needed on issues of FP and RH. “Sometimes they are too

responsive to USAID.” “They need to make more strategic decisions on which studies to undertake instead of doing whatever USAID says to do.”

Research Focus

Another theme that emerged was that CTR is often seen as having a narrow research focus that is largely uninformed by input from service delivery CAs, providers, and users. Whether this is a legacy of its biomedical clinical testing origins or reflects the fact that CTR has only one fully functioning field office is unclear. One respondent stated, “The clinical research approach has had an effect on how they do OR [operations research]. It has led to too much central control and less capacity building [in the field]. It also affects the kinds of questions that are asked. Is A better than B when what’s important might be less defined or overlapping.” Several others stated that there is a need to “frame issues for the researchers,” based on experiences from programs in the field, to allow them to better understand the “reality of providing services.” This kind of feedback is what will close the research to practice gap. Currently, “people’s perspectives and preferences about contraceptives are not well integrated into R&D.” CTR needs to “meet the needs of the consumer up front.” “They should go out and learn about people’s perspectives and then do research based on those perspectives—give more attention to this kind of information.” Such grounding would have an impact on CTR’s research portfolio that was characterized by one respondent as “dabbling rather than strategic and focused.”

Research to Practice

While FHI was praised for disseminating research findings to the research community and policymakers through publications, presentations, and workshops, making an impact on provider practice and client behavior was described by many as an important new obligation for FHI and all research organizations in concert with service delivery organizations. “FHI is relatively new to the research to practice concept, therefore [it] is still on the steep part of the learning curve.” “FHI needs to do more direct advocacy work with research data, publishing in journals is not enough.” Some respondents noted that research results are often presented at forums attended only by other researchers; mechanisms need to be in place to expand the audience. Given the recent importance placed on evidence-based medicine and the need to make research relevant to public health goals in a shrinking resource environment, the urgency for research to practice is growing. Respondents confirmed this new research environment and expressed the need for funding mechanisms that will facilitate the process. “FHI, like other research agencies, doesn’t have specific demands in their [current] agreement to put research into practice.”

Field Presence and Capacity Building

One perception generally shared by those interviewed in both the field and the United States is that the current CTR project is too headquarters based. Comments such as, “They need to build more capacity in the field so they don’t have to be flying in and out,” and “We worked with them on a study. It would have been easier if they had more technical skills in the field.” Others commented, “We would like them to develop more capacity here [in the field], especially in the areas of biostatistics and data analysis.” Several respondents indicated that maintaining rigorous quality control standards during

the research process—by performing most of the data analysis centrally—seemed to be more important to FHI than building capacity in the field.

Management

Respondents raised several management issues as weaknesses. A few recommended that FHI decentralize decision-making. “If top leadership is not available, it takes a long time for them to make decisions.” “Things can move very slowly as it is a hierarchical organization.” Others felt that CTR’s “clinical studies take inordinately long to complete in some, not all, instances.” For example, “It takes them a long time to get people recruited into clinical trials” relative to successful pharmaceutical companies.

Despite recent efforts at interdepartmental and team meetings, there is still the impression that CTR is fragmented; units work separately from each other, and there is poor communication, even within departments. A long-time FHI staff person related the difficulties that the two FHI institutes have had working together as equals. This results in lost opportunities for collaboration in the field between CTR and IMPACT.

Staffing

While the quality and collegiality of CTR staff were unquestioned, some respondents believed that staffing practices were a barrier to project initiation. “FHI tends to address all projects using their internal staff rather than using contractors; this can tend to slow the response to undertaking a project if internal staff are not available.” One respondent commented that FHI is reluctant to increase its staff without adequate future funding and does not want to overextend. As mentioned above, several commented that the Biostatistics Division is understaffed.

RESEARCH QUALITY AND IMPACT

Overview

The goal of the CTR cooperative agreement was “to enhance the freedom and abilities of women and men in the developing world to choose voluntarily the number and spacing of their children.” The purpose was “to develop, evaluate and introduce a range of safe, effective, and acceptable methods of family planning, and to enhance the capacity of FP researchers and programs in developing countries to provide these methods.” CTR and USAID have identified several key strategy areas for accomplishing this, including

- method-specific strategies (female barriers, male barriers, microbicides, hormonal methods, emergency contraceptive pills, male and female sterilization, and intrauterine devices);
- crosscutting areas (maximizing access and quality, adolescent RH, economics of RH services, and HIV/AIDS and contraceptive methods); and
- information dissemination and research to practice.

In order to address these program areas, CTR engages clinical research, health services research, and behavioral and social sciences research, which often interact closely. The

major activities and achievements of this research are described in detail in following sections of this report.

The work of the CTR staff contributes to the following Intermediate Results (IRs) in the strategic framework for USAID's Office of Population and Reproductive Health:

- IR 1: Improved and new contraceptive and reproductive health technologies developed, evaluated, and approved;
- IR 2: Use of contraceptive and reproductive health technologies optimized and expanded; and
- IR 3: Microbicides and microbicides/spermicides developed, evaluated, and approved.

As shown in table 1, CTR either met or exceeded the output targets set as the evaluation criteria in the cooperative agreement (the projected and actual figures are numbers).

Table 1
Outputs for Measurement of CTR Success

Major Outputs/Outcomes	Projected	Actual
Completed phase 2/3 safety and efficacy clinical trials	3	6
Ongoing phase 3 clinical trials	0	3
NDAs and PMAs approved by the FDA and other pivotal trials for registration or measuring method effectiveness	5	5
Countries in which new methods are introduced	5	11
Completed studies to understand and improve method use	50	137
Completed studies on the long and short-term benefits and risks of methods	4	8
Programs to increase contraceptive technology knowledge and skills of researchers and providers implemented:		
▪ publications in peer-reviewed journals	50	370
▪ workshops and conferences	10	101
▪ researchers from less-developed countries collaborating on studies	50	145*
Countries with improved contraceptive guidelines	3	14

NDA: New drug application

PMA: Premarket approval application

* This is the number of subagreements with researchers from less-developed countries; it includes 92 different organizations.

CTR should be commended for this success. Generally, however, this measurement does not show impact in terms of programmatic change and putting research into practice. Addressing this gap has received greater and more explicit attention in the last year and should be encouraged and measured in the next CTR agreement. (See section III, Future Directions, Monitoring and Evaluation.)

As mentioned above, when discussing strengths and weaknesses, there was some criticism of the CTR agenda as being overly controlled by North Carolina and USAID/Washington rather than by the field, and of the lack of strategic vision concerning which studies to undertake. In view of this, **in the future, the CTR research agenda should be determined with greater input from Missions and other country-level stakeholders, such as ministries of health and community groups.**

Contraceptive and Microbicide Research

Over the past three decades, the CTR project has had an integral role in achieving USAID's contraceptive research goals and objectives. In the current cooperative agreement, the illustrative examples of proposed contraceptive and microbicide projects were ambitious and did not adequately reflect the subsequent surge in interest for the clinical evaluation of microbicides. Fortunately, CTR staff recognized the global importance of the HIV/AIDS epidemic and remained flexible in meeting the new demands for barrier and microbicide testing. At the same time, they continued to address opportunities with intrauterine devices (IUDs) and hormonal methods while discontinuing efforts on methods of little or no promise. A major disappointment during the current award has been the failure of any male contraceptive method to advance to a stage requiring phase 2 or 3 clinical evaluations. This is partially counterbalanced by CTR's collaborative research efforts with EngenderHealth that led to significant improvements in vasectomy technique (fascial interposition). These important findings are now being disseminated globally.

The failure to undertake studies with some of the methods proposed in the original scope of work is not a criticism of CTR, but a reflection of the reality that the pipeline for new contraceptive methods did not meet expectations. Correctly, research to maximize access and use of existing methods and to improve continuation rates for existing contraceptive methods has first priority over the introduction of new methods.

The CTR project is recognized as the premier research facility for clinical research among public sector organizations as well as setting international standards for the conduct, analysis, and reporting of clinical research. Moreover, the strategic vision motivating CTR is to conduct world-class research that advances knowledge of contraceptive methods and provides evidence-based findings to improve FP and RH services worldwide. For example, FHI has been a major contributor to the Cochrane database that deals with contraception and FP.

In the current CTR agreement, 150 studies were conducted to

- evaluate contraceptive safety and efficacy,
- assess contraceptive risks and benefits, and
- improve contraceptive method use.

These studies led to the approval of five contraceptive products by the U.S. Food and Drug Administration (FDA)—a laudable accomplishment. More specifically, during the current award CTR staff

- completed six phase 2/3 safety and efficacy studies with condoms, diaphragms, spermicides, vaginal gels, and vasectomy technologies;
- has influenced USAID's discontinuation of vaginal foaming tablets;
- has three phase 2/3 studies with microbicides in progress;
- worked to obtain regulatory approval of the Filshie Clip, eZon condom, Tactylon condoms, FemCap, and the Lea's contraceptive device;

- introduced hormonal, IUD, injectable, or barrier methods in 11 countries; and
- completed an array of studies to improve method use and understand short and long-term risks of contraceptive methods.

In addition, based on results of CTR field studies, USAID no longer provides vaginal foaming tablets and now advocates stopping use of nonoxynol-9 as a spermicide.

Behavioral, Economic, and Programmatic Research

The Reproductive Health Programs Department (RHD) includes the Health Services Research (HSR) Division and the Behavioral and Social Sciences Research Group (BASS). RHD conducts research to understand

- whether and how methods are used by clients and the context of use (BASS) and
- how to improve service delivery, including access, quality, and resource allocation (HSR).

BASS was formalized into a separate group about one year ago and has grown considerably. There are now 14 people in the group; of these, 9 have been with FHI less than three years. FHI's good reputation has helped the recruitment of high-quality staff. One respondent noted that "the ability to attract good people is because of the synergy of the whole place."

HSR focuses on programmatic research on contraceptive technology, with a strong emphasis on improving access. Several of the studies in recent years have come from the "Key Unresolved Issues" section of WHO's *Selected Practice Recommendations for Contraceptive Use*, such as determining the best way to convey to clients what they should do for a missed pill. When asked about the impact of this research, the main findings mentioned were

- use of the pregnancy checklist;
- reintroduction of the IUD;
- female condoms ("they have found a niche for female condoms in South Africa");
- integration of FP into voluntary counseling and testing (VCT) services in Kenya;
- dual protection;
- effectiveness of the cascade training approach; and
- the economics of RH, including cost and cost-effectiveness studies.

This research provides an important base of evidence for international guidance documents and benefits from being in the larger multidisciplinary environment of CTR. According to one researcher in HSR, “Each and every day I talk to MDs and biostatisticians and epidemiologists and economists, and it all helps my research.”

HSR staff members also are praised for its important technical expertise in economic issues; each situation is examined and the approach is tailored specifically to the situation, incorporating both knowledge and flexibility. For example, FHI is currently a partner on both the FRONTIERS and Horizons projects, carrying out economic-related research and building capacity in these skills. This is essential work for providing information for making choices under conditions of constrained resources.

A significant proportion of ongoing CTR studies (39 percent) are taking place in the East and Southern Africa (ESA) Region, with most being conducted in Kenya. Findings of these studies have been disseminated in a number of ways:

- presentations at regional and local conferences,
- end-of-project dissemination meetings,
- production and distribution of reports and briefs,
- organization of special thematic workshops, and
- publication in regional and local journals.

CTR staff members also undertake a number of activities to ensure the use of research results, including working in partnership with key implementing organizations, participating in task forces within the MOH, facilitating stakeholders meetings, assisting with the development of country policies and strategies, and building capacity for using data for decision-making.

As a result of the above, CTR’s research in Kenya has led to a number of changes in policies and programs in the country. In all cases, CTR staff stressed the importance of creating partnerships with a wide range of stakeholders. In particular, MOH representatives in Kenya spoke highly of the work performed by FHI, stating that because CTR responds to requests from the MOH, they are ready to use the findings when they appear. Shown in table 2 are some key examples of the use of research, all of which were mentioned by MOH staff during interviews conducted by the team. The important question now is how CTR can achieve similar results in countries where it does not have the same level of field staff or Mission support. (This is discussed in detail in the following section, Research to Practice.)

Table 2
Highlights of CTR Research and Use in Kenya

Research Activity	Result
Research project on condoms (1998)	Informed the development of the first national condom strategy in Kenya
Study on risks or complications of IUD use among HIV-positive women (1998)	Informed the development of a National IUD Rehabilitation Strategy
The Female Condom Community Intervention Trial (2000)	Influenced the delay in the introduction of the female condom into the general population by the MOH and donors because findings showed the female condom to be a niche product rather than for the general population
Menstruation requirements as a barrier to contraceptive access in Kenya (2000)	Led to the development of checklists to rule out pregnancy and thereby increased access to contraception for nonmenstruating women
Assessment of the Effectiveness of the Cascade Training Approach	The MOH adopted the cascade training approach; FHI/IMPACT will use this approach in VCT training in Kenya
Family Planning in VCT Programs (2002)	Informed the development of a draft strategy for integration of FP into VCT programs
Ability and willingness to pay for FP services (1999)	Informing the development of a pilot MOH/POLICY Project program on FP fee for service

Although there is communication across and interaction among the different divisions of CTR, there is always room for improvement. For example, respondents mentioned the need to initiate behavioral studies earlier in the product development process so that products with no user perspectives could be taken into account. In addition, there were times when more careful formative research should have been conducted before initiating field research. A good example of this is a study in Kenya that planned to explore whether dual protection messages increase the use of condoms by adolescents. After a significant amount of time and money was invested in this study, the CTR/TAC suggested that a process evaluation be conducted. When the evaluation was completed, the results showed that a large proportion of the adolescents already were aware of the dual protective properties of condoms, and that the two different messages being compared were not easily distinguishable from each other. To minimize this, **attempts to determine whether or not an intervention is feasible should be initiated earlier in the research process before a significant investment is made.** This could include involving the CTR/TAC in assessing the importance, relevance, and feasibility of proposed research.

Research to Practice

The idea of putting research into practice is not new to the CTR project. With the start of the Research to Practice (RtoP) Initiative in 2001, however, there is now an increased emphasis on using research findings, and a more formalized approach is being developed. A respondent described this change as “an evolution rather than an epiphany.” There are two full-time staff members assigned to RtoP, and they have worked to institutionalize a research to practice approach among research and program staff at FHI by conducting workshops with staff and revising several internal forms. Although FHI states that the research to practice philosophy permeates its work, there still seems to be a strong emphasis on publication in peer-reviewed journals as an endpoint to research. For example, in a diagram that shows the 24 steps in the research process, the final two steps are submitting a paper for publication and publication, followed by study closure. ***This highlights the need for FHI to continue efforts to change the organizational culture to one that fully embraces the research to practice perspective.***

To date, the RtoP Initiative has focused primarily on identifying key priorities among existing CTR findings to bring into practice. Using three criteria—a solid body of evidence, public health impact, and likelihood of use—staff identified four key priorities: IUDs, checklists, vasectomy, and the spermicide, nonoxynol-9. In the future, it would be useful to explicitly apply a similar but modified set of criteria when first choosing to undertake studies. As one respondent explained, the CTR project “needs more strategic decisions on which studies to undertake instead of just doing whatever USAID says to do.” **CTR should develop more explicit criteria, with flexibility for choosing whether or not to undertake a study.**

Partnerships are essential for facilitating the use of research. Through collaboration, service delivery CAs help to put findings into operation and make them more useful. In addition, RtoP Initiative staff members are collaborating with other research organizations, primarily the World Health Organization (WHO) and FRONTIERS. For example, following a meeting at WHO in March 2003, several organizations are jointly developing a toolkit for turning research into practice that will illustrate the best ways to analyze and describe the use of research as well as which determinants to highlight.

One of the first activities of the RtoP Initiative has been the reintroduction of the IUD in Kenya. With the objective of increasing the provision of quality IUD services and enhancing demand for IUDs, this reintroduction is being undertaken as a four-step process:

1. issues identification,
2. developing the program,
3. consensus building, and
4. implementing the program.

A key achievement has been fostering local ownership and leadership of this process by the Kenyan MOH, which highlights the important role of the researcher as facilitator. This was clearly evident in the management of the IUD Task Force meeting, which assessment team members were able to attend while in Kenya. One key factor in the success of the process thus far has been the importance of continuous discussion so that the issue is not forgotten. CTR has appropriately handed off implementation of the program to AMKENI, an RH service delivery project funded by USAID/Kenya, with CTR as a partner. ***The lessons from the reintroduction of the IUD in Kenya should be well documented and used to help inform future research to practice efforts.***

It is important to note the cost and effort of this work. Slightly less than \$300,000 has been budgeted for the Kenya IUD work, with approximately 75 percent from core funds and 25 percent from field support. CTR staff and USAID need to consider the implications for a future project given the costs of ensuring utilization of research. When asked whether they would consider conducting fewer studies (because adding utilization efforts would increase costs), CTR staff members answered, “We don’t want to rob Peter to pay Paul. There are trade-offs, but we don’t want to ***not do*** so much of our original mandate.” (This issue will be addressed further in section III, Future Directions.)

Kenya CTR staff members acknowledge that there is a need to develop mechanisms to ensure that the experiences from Kenya are shared in the region. Currently, this happens

through discussions with USAID Missions, presentations at regional professional conferences, or when partners working in other countries request CTR's assistance (e.g., EngenderHealth asking for assistance in examining IUD use in Ethiopia). There is, however, a need to formalize this process; it happens, but CTR needs to be more strategic in ensuring that lessons learned are shared with other countries. To facilitate this process, **CTR/Nairobi should coordinate with the Field Information and Training Services (FITS) Department to expand its research expertise and lessons learned to other countries in the region.**

Communication is a key factor in turning research into practice. According to FHI, "the ability to communicate in a timely, accurate way is key to the success of CTR." For example, *Network* reaches more than 70,000 subscribers in English, Spanish, and French (24 times more people in Africa than the *Lancet*), and is also the means for other information dissemination. In addition to *Network*, the CTR project has produced a variety of more targeted communication products in association with the new RtoP Initiative. Thus, as part of the reintroduction of the IUD in Kenya, a series of easy-to-use method briefs, *A New Look at IUDs*, was produced and disseminated.

Product Quality and Compliance Group

The Product Quality and Compliance (PQC) Group is located at a facility separate from the main FHI headquarters. This facility houses a two-shift, production-line testing laboratory, but the expertise of PQC staff reaches far beyond this. Indeed, PQC incorporates the core FHI attributes of a high-quality, internationally acclaimed, client-responsive operation provided by an experienced and skilled technical staff.

The history of PQC dates back to 1988 when USAID requested that FHI implement a program to ensure the quality and appropriate testing of contraceptives procured and distributed in the field by USAID. Given the nature of condom production and testing, PQC devotes the majority of its resources in 2003 to

- establishing standards for condom testing,
- functioning as a rapid response team for problems associated with contraceptive commodities, and
- assessing the quality and uniformity of condom testing performed by manufacturers around the world. (PQC is the preeminent laboratory—there are only two—in the world with these performance and testing capabilities.)

More recently, performing quality assurance testing of each lot of condoms (100 percent testing) manufactured in the United States and procured by USAID was added to its mandate.

PQC works closely with USAID/GH/PRH/CSL to establish product specifications and prequalification of potential suppliers and to assist in resolving product and contract disputes. For example, before the current focus on condom testing, PQC staff participated in surveys of the quality of oral contraceptives, IUDs, and depo medroxyprogesterone acetate (DMPA, an injectable contraceptive). To accomplish this, a state-of-the-art testing facility was established within CTR in 1994 that had the capability of testing all

contraceptive products. The facility is now accredited by the American Association of Laboratory Accreditation and conducts tests in accordance with relevant international standards.

Over the years, PQC has provided technical assistance at the field level to programs in 12 countries in the areas of quality assurance, product evaluation, standards development, training on standards, handling product complaints, and enhancement of laboratory capacities. PQC also works with organizations and companies to provide shelf-life information for contraceptives under development. Moreover, PQC collaborates with other CTR staff on in-house studies to assess and verify the quality and stability of the clinical trial supplies used in research studies, such as those involving the assessment of female and male barrier methods as well as quality assurance of compounds for use in nonsurgical voluntary sterilization procedures. In addition, PQC—in collaboration with USAID, the Program for Appropriate Technology in Health (PATH), WHO, condom manufacturers, and standards organizations—has made substantial progress over the years in ensuring that quality condoms with substantially longer shelf lives can be consistently manufactured and appropriately stored and distributed to users.

MANAGEMENT AND FINANCIAL ISSUES

According to its self-assessment, FHI's management structure and administrative systems have evolved over many years as the organization has grown and diversified its sources of funding. In recent years, however, the magnitude and pace of growth has accelerated to the point that major restructuring was required. During the past year, FHI split into two parallel institutes (Institute for HIV/AIDS and Institute for Family Health), with each headed by a president and chief operating officer (senior vice president for operations)—a new position created to relieve the president of many day-to-day management and administrative duties. In addition, until two years ago, the president of the Institute for HIV/AIDS was not a voting member of the board of directors. In the past, this led to some disharmony because the size and annual budget of the Implementing AIDS Prevention and Care Project (IMPACT), which is under the Institute for HIV/AIDS, was considerably larger than that of the Institute for Family Health (IFH). Fortunately, this situation seems to be coming to a resolution. One remaining aspect of FHI's corporate structure still to be addressed is the board of directors. As FHI's and therefore CTR's strategic planning are affected by actions of the board, **FHI should review the tenure and composition of its board of directors. In particular, attention should be paid to increasing representation from developing countries and abiding by term limits.**

Strategic Planning and Coordination

FHI's strategic planning process dates back to the mid-1980s and has evolved in parallel with the growth and increasing complexity of the organization. At present, accomplishments are tracked against four major goals that were established in 1997 through a consultative process that took several months to develop and involved staff at all levels, including field staff and board members. The current Strategic Planning Committee, which is comprised of eight members (two from each institute and four from the office of the chief executive officer [CEO]), was established in 2003 with the creation of the two institutes. The committee meets quarterly and has a vital planning and oversight role within FHI. Because of the increasing involvement of the IFH in HIV/AIDS research and programs, **the two institutes should work more closely than**

they do in developing their work plans, both at headquarters and in the field, to take advantage of potential synergies (e.g., shared country offices and selected operations research that benefits both institutes).

IFH has four committees that operate at several levels. These committees are scheduled to meet on a monthly basis and serve to facilitate communication and to coordinate work on CTR and related projects among the institute's four departments. The major purpose of these committees is to enable FHI's corporate office and the IFH executive office to

- provide for planning and oversight, regulatory affairs and quality assurance, monitoring, evaluation, and reporting; and
- facilitate support from information technology, human resources, and finance and administration—corporate functions shared by both institutes.

Because FHI's management structure and administrative systems have undergone extensive reorganization within the past two years, **during the remainder of the current agreement, the CTO should ensure that these new IFH committees are functioning as expected (i.e., providing improved communication and oversight as well as enhancing implementation of CTR's annual work plan).**

Role of CTR Within the New Institute for Family Health

Before 1995, the CTR project was the major source of funding for what has now become the IFH. As a consequence of the AIDS pandemic, FHI has had a key role in the fight against this disease through its current and previous HIV/AIDS prevention and service delivery awards since the early 1990s. At the same time, the role of CTR has shifted from contraceptive development to focusing on R&D of male and female barrier methods and microbicides. In addition, IFH through CTR now has become heavily involved in conducting and coordinating microbicide R&D with the Contraceptive Research and Development Program (CONRAD), various divisions of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), several private companies, and, to a lesser degree, the Population Council. (As mentioned above, this large and diversified growth ultimately led to the creation of two institutes in order to better plan, manage, and administer this expanded portfolio of product development activities and field services.)

CTR is now implemented by four departments within IFH, each with specific areas of expertise (see table 3). Of the four departments, the first three (CRD, RHD, and QSD) represent the reorganization of functions that have been an integral part of CTR for many years. Members of these departments work together in multidisciplinary teams to address both the contraceptive and microbicide R&D needs and supporting behavioral, social science, and economic studies. The fourth department (FITS) pulls together several existing but somewhat unrelated functions (e.g., linkages with field offices and dissemination of CTR research results) with the new RtoP Initiative, which includes training to improve provider practices and implementing best practices. Because certain components of FITS are new and the activities within it quite diverse, **during the remainder of the current agreement, the CTO should regularly check to ensure that the stated objectives of FITS are being met and that the department is coordinating with field offices and host country partners.**

Table 3
IFH Departments and Functions

Department Name	Major Functions
Clinical Research Department (CRD)	Carries out clinical trials and epidemiology studies
Reproductive Health Programs Department (RHD)	Carries out behavioral, social science, and quality of care studies in support of CRD
Quantitative Sciences Department (QSD)	Provides biostatistical and data analysis in support of CRD and RHD
Field Information and Training Services Department (FITS)	Provides links with field offices and programs; disseminates research results

Role of the CTR Technical Advisory Committee

The TAC has a long history of advising FHI on research issues. Current members who were interviewed praised FHI for competently managing the TAC, including appointing people who are well qualified and interested in working collaboratively. Until recently, however, the impression by several members interviewed was that the TAC placed too much emphasis on overly slick presentations and did not allot enough time for discussion. This overall impression of the TAC has changed. Now the TAC is seen as having an increasingly important role in advising CTR, especially with research issues where there is genuine disagreement within the organization. Although members now believe that the TAC influences CTR in some areas, it is still perceived as functioning largely as a reactive body.

CTR East and Southern Africa Regional Office (CTR/Nairobi) and Staff Needs

At present, FHI has a regional office in Nairobi, Kenya. It also has a country office in Ethiopia and locally hired staff in several other countries (Haiti, Madagascar, and South Africa) that support, oversee, and facilitate implementation of CTR research and promote research use. During this assessment, the team traveled to Kenya to conduct a site visit of the CTR/Nairobi Regional Office and to assess FHI's implementation support of the CTR project (see appendix C, Kenya Trip Report).

In the field, CTR/Nairobi staff members collaborate and are partners with various agencies and organizations in order to successfully conduct studies and implement activities. While the team was only able to visit study sites in the Western Province (Kericho, Kisumu, Nandi Hills, and Vihiga), CTR/Nairobi participation and technical expertise were highly regarded in all sites visited. CTR/Nairobi also has excellent relations with AMKENI, a USAID-supported bilateral project with which CTR/Nairobi is a partner, both in the field and in Nairobi. Moreover, the German Technical Cooperation (GTZ), with whom CTR/Nairobi is collaborating on projects aimed at preventing unwanted pregnancies and HIV/AIDS in adolescents in Vihiga, is very pleased with the technical assistance, responsiveness, and flexibility that CTR/Nairobi provides.

During the past few years, the CTR/Nairobi office has undergone considerable growth (from 2 to 10 professional staff), not only in size and funding but also in expanding the

technical capabilities of existing staff to design, implement, and analyze high-quality research studies. FHI has actively supported and contributed to this through a partnership process (e.g., linking CTR/Nairobi staff with CTR/headquarters counterparts). Kenyan staff members believe that this partnership process

- is very interactive (“there is room to say your view”);
- has given local staff important opportunities based on interactions with each other (i.e., there is a sense of teamwork both within the office and with CTR/headquarters); and
- has improved the relationship between CTR/headquarters and the field.

The only perceived shortcoming to the partnership approach is that “when everyone has to look at things, getting everyone around the table at the same time is difficult and can slow down the process of developing and implementing research or programs.” Despite this limitation, to further reduce the need for staff to fly into Kenya routinely, **CTR should continue to strengthen the Kenya office so that it becomes more independent, including allowing people to pursue further education.**

There is also a need for additional technical capacity in biostatistics and data analysis. This could be accomplished either by increasing the knowledge and skills of existing CTR/Nairobi staff or by bringing in new technical staff. (USAID/Kenya seconded the need for CTR/Nairobi to have additional technical capacity, including having more technical staff.) **CTR should continue to support strengthening the technical capabilities of CTR/Nairobi in design, data collection, data analysis, and reporting of research and program activities.**

CTR is to be commended for its focus on introducing good research practices in Kenya. These efforts, however, should continue in ways that do not unduly interfere with or delay studies on local issues. Moreover, CTR should be encouraged to continue its leadership role in transferring good research practices in all its international research work.

Resource Allocation To Maximize Efficiency and Effectiveness

CTR funding is allocated to FHI according to a system that establishes the priority of technical resources relative to major CTR project needs. These priorities are reflected in the annual work plan and budget that are determined through extensive consultation with the USAID/GH/PRH/RTU. In addition, the CTR/TAC annually reviews the research priorities. As described in the self-assessment, USAID’s long-term investment in CTR has enabled FHI to develop multidisciplinary teams of highly skilled, experienced scientists and public health professionals capable of conducting high-quality clinical, behavioral, and programmatic research for CTR as well as other agencies (e.g., CONRAD and NIH). In theory and in practice, the synergies of skills and expertise within the three departments described above (CRD, RHD, and QSD) would be difficult to achieve if they were to be separated through a consortium of organizations.

As FHI grows and takes on added functions (e.g., the new elements in the FITS Department), the potential need to go beyond the organization for technical assistance,

and hence the need for forming partnerships, may diminish. In fact, several respondents expressed concern that increased internal capability leads to decreased interest in seeking outside assistance or funding. In addition, the perception exists that the demands for quality control in large-scale microbicide trials are counterproductive in terms of forming partnerships. Because establishing partnerships with governments, nongovernmental organizations (NGOs), and other donor agencies is a key strength, **CTR/FHI needs to explore ways to ensure that wherever possible, collaboration and forming partnerships with host-country counterparts and other agencies and organizations continues to occur.**

Management and Staff Changes Needed To Improve Efficiency

Cumbersome Work Plan Development Process

One of the consequences of the current work plan/budget development process is that subprojects to be implemented within a work plan period are identified before the beginning of the work plan year, and the final cost objective, concept proposal, or preliminary approval letter process is initiated at the time the annual work plan is finalized. All subprojects, however, do not begin at the same time because CTR technical monitors often are not ready to begin developing new subprojects at the beginning of the new work plan year (July 1) for various reasons (e.g., busy completing other ongoing work, or travel to potential implementing sites may be delayed). Consequently, in some cases, there may be a long lag time between submission of the preliminary approval letter and the approval to implement the request, leading to problems launching the subproject.

For the short term, CTR has decided to delay submission of the preliminary approval letter to the cognizant technical officer (CTO) until the technical monitor is ready to begin study development to see if this decreases the lag time. The long-term solution, however, would be to change the proposal review and signoff mechanism for the remainder of the current cooperative agreement, or at least in the follow-on project. For example, formal signoff on the annual work plan by the CTO would then serve as authorization to proceed with new subproject development. A preliminary approval letter would then be needed only if additional ideas arose during the course of the work plan year. This work plan signoff system is standard practice in other cooperative agreements; however, implementing this process for CTR would require submission of a more detailed proposal (not just a concept paper) and an accurate first-year budget (with all indirect costs included) in order for the CTO to be able to formally commit to the proposed subproject. If this system were adopted, then final cost objectives would need to be assigned only for those subprojects that are agreed upon by USAID for inclusion in the work plan. As long as each proposed project in the annual work plan has sufficient detail, **USAID should consider formal signoff on the annual work plan by the CTO as authorization to proceed with new subproject development.**

Frequency of Scheduled Meetings of FHI's Institutional Review Board

In the self-assessment, the fact that FHI's institutional review board, the Protection of Human Subjects Committee (PHSC), only meets quarterly was presented as one of the causes for delay in implementing and completing subprojects. Technical staff at FHI headquarters perceived this to be a problem until recently. Apparently the PHSC is now prepared to meet on an as-needed basis. Given the increasingly heavy project load at FHI,

if this problem persists or recurs, **FHI should consider outsourcing the less complicated studies to a commercial review board, such as Western Institutional Review Board, to facilitate this process.**

Need for Additional Staff

In the self-assessment, FHI proposed the need to hire many new types of research and public health professionals under CTR (e.g., physicians and epidemiologists with HIV/AIDS service delivery and clinical expertise, economic experts to measure cost and effectiveness, and additional field staff to expand the RtoP Initiative). The importance of adding these new capacities needs to be carefully considered by USAID for several reasons. First, other service delivery agencies already have HIV/AIDS expertise, and there are a number of excellent university-based groups (e.g., at Georgetown and Harvard) with extensive experience in measuring cost-effectiveness. Second, with limited core resources, adding new areas of expertise without an increase in CTR funding would draw resources away from essential activities. For example, the most critical need expressed in the interviews was in the areas of biostatistics and data analysis—both to support CONRAD and other agencies contracting for these services and in the field (see appendix C). Finally, as FHI seeks to become the single source for all aspects of research, development, registration, implementation, evaluation, costing, results dissemination, and use of all contraceptive methods, collaboration becomes less important. **For the remainder of the current agreement, CTR should collaborate with CAs or other organizations having the required expertise (with the possible exception of increasing the capacity of the biostatistics group in North Carolina and Kenya).**

The workload presented to the Quantitative Sciences Department (QSD), however, needs special attention because it fluctuates unpredictably because of requests from various stakeholders external to FHI (e.g., CONRAD, NIH, and USAID Missions). Because this work is perceived as a service function that contributes to delays in responding to requests, **FHI should be encouraged to identify and use reliable, quality outsourced contractors to augment internal staff in order to meet peak demands that exceed the capabilities of full-time staff.**

PORTFOLIO ASSESSMENT

Contraceptive and Microbicide Research Relative to CONRAD and the Population Council

The USAID-supported cooperative agreements for the contraceptive and microbicide programs at CONRAD, the Population Council's Center for Biomedical Research (CBR), and CTR supplement and complement one another. While both CONRAD and CBR continually review the findings of basic research and rapidly assess this knowledge base to identify new leads, all three programs assess and select leads brought to their attention by the academic and pharmaceutical/biotechnology communities.

Development of Potential Contraceptive and Microbicide Products

The Population Council

CBR works predominately with its own or in-licensed proprietary candidates that are protected either by patents, technological knowledge, or new drug applications (NDAs). Product leads are for the most part proprietary to the Population Council. This requires that USAID work with CBR for those product candidates of specific interest to USAID.

The number of contraceptive candidates under development at CBR, however, is limited by the lack of innovative new product leads. The CBR portfolio of male and female contraceptive and microbicide drug candidates essentially represents the state-of-the-art in these areas. The limited dimensions of the pipeline, however, do not minimize the potential impact that the modest list of product candidates could have on contraceptive use. Current CBR product candidate leads in female hormonal contraceptives are incremental but significant additions to the broad array of methods that are now commercially available. Newer progestogens with different pharmacologic profiles offer opportunities for either

- improved safety and acceptability (e.g., related to fewer or less objectionable side effects);
- perceived ease of use in selected populations (e.g., breastfeeding women); or
- improved design of delivery devices (e.g., extending vaginal ring use to one year).

CBR is using its proprietary steroid, nesterone, in combination with its considerable expertise in delivery systems to provide new products using vaginal rings, gels, and patches as delivery mechanisms to increase user acceptance. These improvements, even though incremental, continue to be significant for expanding the contraceptive market.

The Population Council through CBR also is working on a nonhormonal drug candidate (a lonidamine analog) for male contraception. This drug candidate works via purported premature release of germ cells from the seminiferous epithelium. Technical and financial support from CONRAD (using funds from USAID and other donors) to CBR has contributed significantly to the successful and timely development of this lead. If preclinical research continues to look promising, this drug could provide a truly significant addition to contraceptive choice and male involvement.

CBR's entry into the microbicide field is Carraguard. The specific proprietary carrageenan fraction used in Carraguard is a substance adopted from the food additives industry. It should prove to be quite safe in use and could probably qualify for an over-the-counter designation by the FDA. Carraguard could enter a phase 2/3 study at about the same time that FHI starts the Savvy (vaginal gel surfactant) and cellulose acetate clinical trials (see section III, Future Directions, Contraceptive and Microbicide Research).

For those candidates that are in its portfolio, CBR exercises (through its proprietary positions and in-house development capabilities) close control over the timeliness with

which an entity can be developed and over the eventual commercialization of product candidates through industrial partnerships. By having the means and accountability for in-house drug development at CBR, each product candidate benefits from having the indispensable product champion working to ensure its success throughout the development process.

The CTR project has contributed data analysis, protocol suggestions, and administrative procedures (such as assisting with the preparation of standard operating procedures) to assist CBR with its newly expanded role of conducting phase 3 clinical trials. While CTR provided data analysis in support of CBR's scheduled clinical trials with Carraguard, the development of internal clinical studies expertise and the intended use of contract research organizations to augment the capacity of CBR make any further involvement with CTR by CBR in the clinical assessment of Carraguard unlikely. Moreover, it is the team's opinion that CBR will not call upon CTR for assistance in the conduct of data management for or analysis of any contraceptive or microbicide clinical trials.

CONRAD

CONRAD, using several funding mechanisms, has a wider array of contraceptive and microbicide projects than CBR. For example, CONRAD supports the development of

- a number of alternative and improved systems for the delivery of established steroids to be used either as female or male contraceptives,
- spermicides for vaginal delivery, and
- barrier methods, such as cervical caps, diaphragms, and female condoms.

The net contributions of these potential products are additive rather than substitutive in the market. For example, the female hormonal methods make sense to develop because of their low-risk profiles, high degree of acceptability, and the programmatic familiarity associated with these well-characterized synthetic hormones and their delivery systems.

CONRAD, through its Consortium for Industrial Collaboration in Contraceptive Research (CICCR) and Global Microbicide Project (GMP), also supports the development of a number of microbicides with mechanisms of action classified as acid buffers, surfactants, entry inhibitors, or replication inhibitors. Through appropriate planning, expeditious early-stage evaluation, and product development, CONRAD extends the breadth of microbicides identified and available for subsequent clinical development by CTR. (CONRAD is the principal source of drug candidates that CTR evaluates in the clinic.)

Other Collaborative Relations

Other relations between and among the various agencies include the following:

- FHI collaborates with PATH by providing data management and analysis support for the evaluation of a new female condom and the SILCS diaphragm under development at PATH in conjunction with CONRAD.

- FHI provides support to WHO with USAID funds, but no funds directly support clinical or programmatic research on new contraceptive or microbicide leads.

Primary Focus of the CTR Project

In contrast to the above organizations that have drug discovery missions, the primary focus of the clinical research component of CTR is to evaluate the safety, effectiveness, and acceptability of new and existing contraceptives and new microbicides. CTR provides credible, efficient, and reliable clinical trial, data management, and data analysis support for both contraceptive and microbicide product candidates. For example, CTR is an expert in conducting large, multicenter, international clinical trials, including those that are pivotal for regulatory submissions. CTR also has developed extensive resources in behavioral, economic, and health services research that complement the early phases of the drug development work by CONRAD. The technical support provided by CTR for assessments of safety, efficacy, and acceptability is a complementary and necessary component of the R&D programs at CONRAD as well as at NIH and their grantees.

Up to the present time, CTR has relied on new contraceptive and microbicide candidates flowing from CONRAD's pipeline. As mentioned above, the pipeline for truly innovative contraceptive drug candidates has become relatively sparse at CONRAD as well as in the laboratories of those international pharmaceutical companies that are traditionally involved in contraceptive research.

Among CONRAD, CBR, and CTR, it is the latter that will need the largest funding increase to support the anticipated number of microbicide clinical trials. CTR is already providing study design and analytical support for a number of microbicides under development at CONRAD that could begin phase 2/3 trials in 2004. FHI conservatively estimates a cost of \$12 million per study (the consensus estimate is about \$38 million per study, however). Assuming it takes four years to complete a study, and potentially up to three studies will be ongoing at a time, ***an additional \$12–38 million per year will be required to support microbicide studies at CTR and to avoid a negative impact on CTR's normal research agenda.*** These additional funds will need to come from other USAID sources supporting HIV/AIDS research, global AIDS programs, multinational donors, or private foundations (see section III, Future Directions, Funding Mechanisms for details).

Rationale for Supporting CONRAD, The Population Council, and FHI

USAID support of these three organizations provides a much greater opportunity for success in USAID's mission to develop new and improved contraceptives and microbicides than would exist if funding to any of them were discontinued. The three institutions regularly exchange information in meetings of advisory boards and TACs. In addition, CTR is supportive of and can provide significant intellectual input to the product development programs at both CBR and CONRAD.

In practice, the bulk of programmatic collaboration occurs between CTR and CONRAD. The clinical research components of CTR and CONRAD provide a continuum for the development of USAID-supported drug and device/product candidates. While CONRAD's pipeline funds the clinical trial program at CTR, the latter in turn provides

data management and biostatistical analysis support to CONRAD. This precludes the need for CONRAD to duplicate an expensive skill set. CTR's working relationship with CONRAD functions well, seemingly from the collaborative institutional culture provided by senior management at the two institutions as well as from the spirit of cooperation and collaboration that exists among project participants at the implementation level. Having three CAs engaged in drug discovery and product development research provides USAID with

- increased program breadth,
- access to potential products of a proprietary nature,
- the ability to influence financial support, and
- an overall increased opportunity for innovation and success.

In addition, continuing to support these agencies is more important now than it has ever been before because these two areas of research—contraceptives and microbicides—have become critically dependent on public sector support due to the exodus or lack of interest of industry. In view of this, **USAID should continue to support CTR, CONRAD, and the Population Council (CBR) in their critical R&D efforts to provide the public with new or improved contraceptives and new microbicides.**

Program Research Relative to FRONTIERS and Other Operations Research

Although multiple USAID-funded organizations engage in operations research (OR), the two primary agencies involved in OR are FHI, through its HSR Division, and the Population Council, through FRONTIERS and Horizons. The research in CTR's HSR Division is programmatic research on contraceptive technology and is motivated by FP methods. As described in the CTR cooperative agreement, "FHI's focus in this work continues to be on the contraceptive methods themselves, with the ultimate goal of improving access to an expanded choice of affordable methods provided in programs of high quality." For FRONTIERS, the focus is more on systems; its OR generally "does not start with a method, but looks at the situation of program managers." The portfolio of FRONTIERS includes very little in terms of promoting new or underused methods, whereas this is a key role of CTR. Research themes in the FRONTIERS project include FP and related health issues, such as safe pregnancy, reproductive tract infections, HIV/AIDS, and eradication of harmful practices, such as female genital cutting.

The overlap between FRONTIERS and CTR is fairly modest and is mostly in the area of integration, an increasingly important area that can benefit from having multiple organizations addressing it. As one respondent explained, "The nature of our relationship is that we'd rather look for ways to work together, so there won't be much overlap between what we do." Moreover, most FRONTIERS studies address local questions and are implemented largely by country or regionally based researchers while CTR programmatic studies tend to be centrally controlled.

In addition to the fact that there is little overlap between the CTR and FRONTIERS portfolios, there are also many benefits to having multiple organizations involved in OR. Respondents mentioned that there is more innovation, creativity, and choices with multiple organizations, and that better products arise from organizations with different approaches and ideas. As an example, CTR and Population Council staff recently worked together to develop a list of OR priorities for USAID; most likely, this was a better

product than if developed by only one organization. **USAID should continue to support the OR programs of both CTR and FRONTIERS. In addition, USAID should continue to encourage collaboration among the various groups conducting OR in terms of sharing findings, methodologies, and lessons on improving the transfer of research to practice.**

III. FUTURE DIRECTIONS

INTRODUCTION

The current CTR agreement began in August 1995, one year after the pivotal International Conference on Population and Development (ICPD) in Cairo. ICPD helped to expand the perspective of the population and FP field to look more broadly at reproductive health. Now, almost 10 years later, FP is at risk of becoming lost due to the dominance of HIV/AIDS in public thinking and donor funding.

When this agreement began, HIV/AIDS was already a significant concern. The CTR project therefore included a strong focus on barrier methods due to their dual protection potential. Funding priorities and attention have shifted dramatically towards HIV/AIDS while resources available for FP have decreased. With over 42 million people currently infected, HIV/AIDS programs clearly need this increased funding.³ However, it is important that the global RH community not lose sight of the unfinished agenda and continuing need for improved access to quality FP services. There are nearly 230 million women in the world who lack information and access to a full range of contraceptive methods, and more than one third of all pregnancies (80 million a year) are unwanted or mistimed.⁴ As one respondent explained, “One is worried that the large amount of money in microbicides pulls people away from other work.” While acknowledging the importance of work on microbicides, a respondent expressed concern as to “who will do the plain vanilla stuff making the FP program work?” CTR has a critical role in ensuring that there is a continuing focus on strengthening FP services and improving the field’s knowledge of how FP is affected by HIV/AIDS. It is essential not to lose focus on contraceptive development and FP services in a field that is becoming increasingly dominated by HIV/AIDS. Towards this end,

- **USAID should ensure continued high levels of funding for FP and**
- **CTR should ensure a continuing focus on improving FP programs.**

The structure and functioning of USAID has also undergone a number of changes since the current CTR agreement was awarded. In particular, the process of decentralization has given a great deal of independence to USAID Missions. Many respondents believed that lessons learned from core-funded research are not always incorporated into Mission programs, and that USAID/Washington should “make sure our own staff [Missions] know what are the things people should be adopting.” In addition, Missions are often not supportive of research in general, or even allow core-funded research studies in particular to be conducted in-country. Because of this, **USAID/Washington should be more proactive in encouraging Missions to use best practices in country programs and to support important research activities through both core funding and field support.**

PROPOSED CONFIGURATION

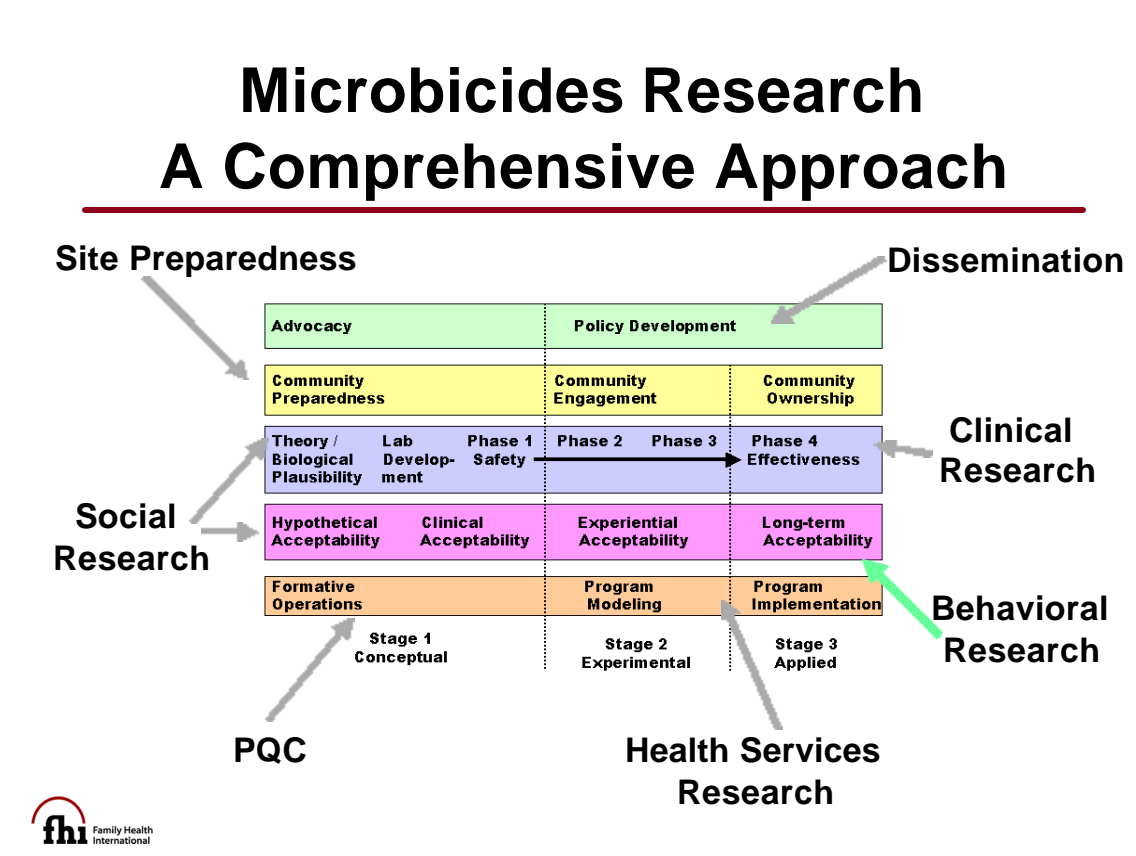
The CTR project has flourished under two conditions—longevity and consistency—both of which are highly unusual for USAID-funded projects. Nearly 30 years of ongoing funding and supportive leadership have created a project with tremendous depth and

³ UNAIDS, *AIDS Epidemic Update*, Geneva, December 2002.

⁴ Family Care International, *Sexual and Reproductive Health Briefing Cards*, New York, 2000.

breadth. Initially focused on carrying out clinical trials of contraceptive methods, CTR has grown to embrace behavioral, economic, and programmatic research and to create methods and high standards for how this research should be conducted in the developing world. CTR also ensures the quality of condoms and other FP methods through PQC and is committed to bringing research results to bear on policy and use through its RtoP Initiative.

The figure below aligns current CTR components with project objectives.



When asked whether the follow-on CTR project should retain its existing components, the reaction of those interviewed for the assessment is telling. Many seemed slightly resentful of the unique advantages FHI has enjoyed in its relationship with USAID yet still endorsed maintaining the broad capabilities represented in the current project.

“I’m envious of them. They can call on a biostatistician; can build in-house teams and that helps put science forward.” “It streamlines efforts when capabilities are in-house.” “An in-house statistician is more familiar with the issues, can give more conceptual thought to the project as compared to bringing in assistance from outside; it is hard to come in out of the bullpen and do good data analysis for behavioral or clinical data.” “I’d keep the project as is. The scientific depth makes it more credible as an advocate for change.” “It doesn’t make sense to do it without all those pieces in there—crazy to try to farm those pieces out and still achieve the synergies necessary to do this biomedical research.” “CTR’s current technical breadth has allowed it to be responsive. In the PH [public health] world when things change so rapidly, an organization needs to be flexible in order to

focus on what's relevant." And finally, "I think this [CTR] has worked—USAID needs to think carefully before they dissect it."

Clearly, the consensus of opinion is that USAID should continue to support a project with broad capabilities as long as it is producing a relevant, quality product. **The follow-on CTR project should maintain the same components and capabilities—clinical, behavioral, economic, and programmatic research; product quality testing; and research to practice—found in the present project.**

A good deal of reorganization has recently taken place to foster synergy among the different CTR departments and divisions and also between the new FHI Institutes—synergies that the team believes have not been fully exploited. To be successful, this move to enhance communication and cross-fertilization cannot be a static process; disciplinary cultures, norms, and even language are often distinctly different. Top leadership must champion interdisciplinary approaches to research and use and reward successful collaborative efforts. If this reorientation proves effective, the potential rewards will be great. One respondent noted, "We must challenge each other across the disciplines—that is so important and leads to innovation." Another stated, "The most interesting things in science [and public health] happen at the borders." The recommendation for continuing the present configuration for the follow-on project comes with the additional directive that multidisciplinary approaches become the modus operandi for CTR activities. At the very least, research questions should be vetted throughout FHI to profit from the different disciplines and approaches represented. **To ensure this, a mechanism should be created in the follow-on CTR project to institutionalize an interdisciplinary approach to research and its use.**

The need to use the results of research and to secure clinical research sites along with the lack of research capacity in the field are recurring themes throughout this assessment and will be discussed in detail below (see Capacity Building in this section). Project composition can have a significant impact on all of these issues. After ending core support for the family health research centers in the early 1990s, the current CTR project has favored more centralized operations and research agendas. For example, only the offices in Kenya and Ethiopia could be considered fully functioning field offices although research is being conducted in several countries (e.g., Haiti, Madagascar, and South Africa) and at other locations as well.

Uptake of research results and best practices is accelerated when country-level policymakers, providers, and users are involved in formulating relevant research questions and carrying out the appropriate studies. This reality is evident in the impact that CTR/Nairobi has had on MOH policies there. When asked about CTR's research portfolio, the director of one of the Kenyan MOH offices responded, "Of course we support it. They [CTR] have been doing the research we asked them to do." In terms of accepting core-funded clinical research, Missions and the MOH are more likely to accede and assist if a strong local partnership exists with research organizations. Moreover, external expertise is less necessary if local talent is identified, recruited, nurtured, and used. **The follow-on project should mandate a stronger field presence than is currently operative. In addition, if FHI is awarded the project, CTR and IMPACT should work together to establish joint field offices and develop complementary work plans.**

CONTRACEPTIVE AND MICROBICIDE RESEARCH

CTR has a primary accountability to remain responsive to the needs for clinical evaluation of the safety, efficacy, and acceptability of new contraceptive drug candidates in the CONRAD pipeline. Unfortunately, those barrier methods currently in development address only niche markets and/or lack attributes attractive to public sector pricing. In addition, the extent to which the hormonal male methods will reach advanced clinical testing is problematic until issues surrounding delivery, contraceptive interval, and cost are resolved. Finally, should any second-generation microbicides prove to have spermicidal properties in the next 5–10 years, their clinical testing can be addressed within the expanding microbicide R&D program at FHI.

Because the contraceptive pipeline is not robust, a reflection of the state-of-the-art of contraceptive R&D, the focus of a follow-on project should be on making existing methods more attractive and widely used. While remaining prepared to undertake the phase 2 and 3 evaluations of those contraceptive candidates emerging from CONRAD's pipeline is important, **CTR should focus on research to extend the safety and acceptance of existing contraceptives and to improve their continuation rates in the next project.**

There is an urgent public health need to develop a woman-controlled vaginal microbicide to reduce the transmission of HIV/AIDS during intercourse. Strong support and demand for such a product exists, both at the public and policy levels. The health consequences of any delays in terms of morbidity and mortality associated with the HIV/AIDS epidemic are enormous. Sixty-seven percent of young people (ages 15–24) living with HIV/AIDS in Sub-Saharan Africa are women.⁵ In Kenya (the site of CTR's only regional office) in 2003, three individuals die from HIV/AIDS every 5 minutes. In view of this urgency, **the team endorses the short-term need for a microbicide-only product, followed as soon as technology and resources allow by the development of a combined microbicide/contraceptive product.**

Conducting the clinical trials required to register a microbicide/contraceptive product will be a challenging task. The microbicide research community also anticipates the development of second-generation microbicides with higher levels of efficacy in preventing HIV seroconversion than those presently proposed for clinical testing provide. Success with either of these, however, will further challenge the capacity to conduct clinical trials.

Role of the CTR Project

There is substantial pressure from microbicide interest groups to proceed with the large-scale phase 2/3 type of clinical trials of multiple (perhaps as many as eight) microbicide candidates. These groups postulate that large use-effectiveness studies (three arm, 4,000–6,000 patients) are the only way to demonstrate efficacy of a microbicide drug candidate in the absence of applicable animal models of verified relevance and/or surrogate markers of clinical effectiveness.

⁵ United Nations Population Fund (UNFPA), *State of the World's Population Report*, New York, October 8, 2003.

CTR has a leadership role in the design of these phase 2/3 clinical trials of potential microbicides. Savvy and cellulose acetate could be the first products to enter this expanded phase of clinical testing, perhaps along with Carraguard, the Population Council's (CBR) drug candidate. All three are scheduled to start patient enrollment in the first quarter of 2004. Both Savvy and cellulose acetate are drug candidates selected on the basis of sound in vitro efficacy, in vivo safety studies, and medical and scientific judgment; however, their relevance still needs to be confirmed in clinical trials. In the next few years, CTR will gain substantial experience in the clinical evaluation of microbicides that will be transferable to other programs at USAID, NIH, and CDC as well as to the field at large. This will result in improved efficiencies in all microbicide research programs. The clinical assessment of Savvy and cellulose acetate also will be important in establishing standards for evaluating the clinical efficacy of all microbicides. Additionally, these studies may provide the opportunity to explore the predictability of surrogate markers of effectiveness in order to make a product candidate available for testing with more targeted acceptability and service delivery features, both of which are needed.

In the absence of any indication of clinical efficacy, CTR anticipates using a two-arm use-effectiveness study with approximately 1,100 women per arm, at an estimated cost of \$12 million for each study (two Savvy trials—one in Ghana and one in Nigeria—and the cellulose acetate trial in Nigeria). Assuming an early 2004 start date, patient follow up could be completed in 2007, with data analysis and regulatory review to follow. Based on this timeframe, successful completion of the two Savvy studies, which would support product introduction with FDA approval, could happen no earlier than 2009—but only if enrollment is accomplished without delays and efficacy is as high as the 50 percent level planned in the statistical design.

By conducting two studies, the statistical power of each can be reduced from the $p < 0.001$ required by the FDA for a single pivotal study to $p < 0.05$ (recommended by FDA to FHI). Doing this simplifies, reduces the size of, and speeds up time to completion. While such a design requires a second pivotal study for FDA approval, the overall program-to-registration time may well be accelerated. Failure to show efficacy in any of these early studies, however, has the potential of being a significant deterrent to the support of other microbicides under development.

Issues With the Proposed Clinical Trials

A number of issues still remain regarding the clinical evaluation of potential microbicides. The most important issues include the following:

- The inability to perform a conventional phase 2 study to assess efficacy using a small number of subjects (100–500) remains a major impediment to the selection and establishment of priority of the proposed array of microbicide drug candidates. For any one, the lack of a small-scale study makes selection of appropriate formulations, dosage, and treatment regimens extremely inefficient. (FHI recognizes this and is working to design an improved process for selection and setting priorities for the other microbicides in the pipeline.)

- At present, there are up to eight drug candidates being readied for clinical assessment at CTR and other organizations. Additional second generation products are in the pipeline. Costs for the present clinical design range from a low of \$12 million per compound projected by FHI to a consensus figure of about \$38 million per compound. The larger trials, which require 4,000–6,000 subjects per study, will require as many as 60,000 women or couples with high-risk exposure to HIV/AIDS, just to determine the efficacy of the present list of clinical candidates. Given the impact these studies will have on the available financial resources and on saturation of clinical sites capable of conducting these studies, **USAID should take the lead in working with its collaborators to implement a selection and priority-setting scheme for those microbicides in the various pipelines.**

- When new science is being explored for early indications of effectiveness, the study design should be kept as simple as possible to best enable an early establishment of merit to the new science. Some of the respondents referred to this stage of clinical testing as establishing the proof of concept. Although the public health needs are indeed real and urgent, simpler objectives at the beginning may be a faster way of achieving registration in the long term. **CTR should continue its focus on early identification of microbicide efficacy and not encumber initial studies with assessment of social and behavioral issues associated with microbicide use. (Specifically, research related to the development and/or introduction of vaginal microbicides should be conducted as separate studies.)**

- The anticipated low levels of efficacy in first generation microbicides along with the per exposure price when using a microbicide are important product characteristics that will have to be considered in light of the low cost of condoms (2.5–5 cents per unit). The logistics of stocking, dispensing, and home storage of a microbicide needs early consideration in the research studies as well.

Despite these concerns, however, **CTR should continue with all possible speed in the assessment of Savvy, cellulose acetate, and any other microbicides CONRAD may offer for clinical testing.** Lacking more innovative designs, CTR's more conservative, streamlined clinical trial design should be used while remaining vigilant for ways in which to further improve upon it. Given the urgency of finding an effective microbicide, time to completion of the study and analysis of the findings are critical dimensions. Therefore, because large-scale studies will of necessity be performed in developing countries that have minimal clinical trial infrastructure, **major resources (equipment and staff) need to be in place, both at FHI headquarters and in-country study sites, to assure real time monitoring of the quality of the data collected and their prompt, electronic transmission to North Carolina for analysis.** Moreover, project team managers should ensure timely completion of all clinical trials, and the scientific excellence of CTR should neither be compromised nor act as a deterrent to achieving this objective.

Role of USAID

USAID has kept the pressure on its collaborators in microbicide research to seek the most efficient design of clinical trials to demonstrate the efficacy or proof of concept before embarking upon large-scale, phase 3 trials. Due to USAID's insistence, significant progress has been made in

- reducing the number of factors to be assessed in a single trial and
- decreasing the overall number of participants in a study.

It is hoped that continued awareness of the need for further improvements in protocol design will reduce the need for the inordinately large investment of resources and will decrease the inefficiencies in drug development still remaining in the clinical trial design. To guide this process, **USAID should continue to encourage the timely resolution of common problems in the clinical development of vaginal microbicides so that clearer and simpler development and registration strategies can be defined.** Doing this would expedite development of the field in general, conserve resources, and make it more attractive for additional pharmaceutical industry participation.

PRODUCT QUALITY AND COMPLIANCE

During deliberations between the assessment team and FHI, it was announced that PQC would henceforth report directly to the senior vice president for operations, further integrating the unit into CTR programs. In addition, upgrading PQC to departmental status in the new IFH is being considered. PQC will benefit from this closer relationship by obtaining an early insight into contraceptive quality assurance, procurement, and testing issues that will arise. CTR will likely benefit from PQC's assistance as well. For example, PQC will be better positioned to provide CTR staff with technical input regarding sourcing, procurement, and the quality of items used in research studies.

While it would be possible to establish a freestanding organization with the same or similar mission of PQC, both CTR and PQC benefit from their integrated association. PQC benefits not only from the programmatic association with FHI but also from the quality image it portrays as being a functional component of CTR. Separation of PQC from CTR would provide neither economies nor efficiencies in their operations. As such, **PQC should remain a component of CTR and its mission should be included as an integral part of the scope of work for CTR in the follow-on project. Moreover, in the next project, PQC should be empowered to**

- **propose new cost-efficient condom testing protocols and automation of procedures;**
- **undertake an expanded mission to design and provide, as appropriate, QC/QA support for the clinical evaluation of the emerging array of microbicide candidates and HIV/AIDS test kits; and**
- **provide inventory management and procurement response guidelines to those organizations providing commodities to USAID.**

BEHAVIORAL, ECONOMIC, AND PROGRAMMATIC RESEARCH

For the next CTR project, priorities for behavioral, economic, and programmatic research should fall under two main categories:

- *increasing the use and continuation rates of existing FP methods and*
- *understanding the integration, interface, and interaction of FP and HIV/AIDS.*

As one respondent asked, “Have we gotten all the mileage out of what’s out there already?” Given the low contraceptive prevalence in many countries as well as high discontinuation rates, there is a need for improved marketing of existing methods and for additional behavioral research to help increase long-term use of contraception. There are a number of methods that are potentially underused, including long-term and permanent methods, male condoms, and fertility awareness methods, such as the standard days method.

Many respondents mentioned the continuing need to understand why condom use remains low. In light of high rates of HIV and sexually transmitted infections (STIs) and the fact that a microbicide will not be available for many years, condoms remain critically important for public health. This highlights the importance of conducting research to understand how to increase male involvement in RH.

A number of respondents pointed out the need to look critically and strategically at method mix and the idea of underused methods. There is a need within each of the different settings to clearly define what underuse means. Just as CTR has looked strategically at underused findings and set criteria to choose priorities, there is also a need to look critically at issues of underused methods. This does not necessarily require new research but rather a thorough review of existing information and consultation with experts, including people outside FHI (e.g., linking with WHO’s strategy for contraceptive introduction).

FHI is recognized as a leader in the area of contraception and HIV/AIDS, and this will remain a critical need under the next CTR award. This includes gaining a better understanding of how contraceptive methods are affected by HIV/AIDS and vice versa. To this end, **in the next project CTR should continue to explore important contraception/HIV health considerations, such as the risk of acquisition among HIV uninfected women and risk of transmission, disease progression, side effects, and antiretroviral therapy effects on systemic hormonal contraceptives among HIV-infected women.**

It is also important to stress how FP can help HIV prevention efforts. “Because unintended childbearing exceeds 50 percent of all births in some countries; goals to reduce the risk of mother-to-child transmission (MTCT) should include more emphasis on preventing pregnancies.” FHI has produced a model that compares increasing contraceptive use to providing antiretroviral therapy during pregnancy and delivery to prevent vertical transmission. This model suggests that contraception is both effective and cost-effective in preventing MTCT of HIV. This calls attention to the importance of integrating FP into MTCT and VCT services, areas that the CTR project is already

exploring and should continue to emphasize. **In the future project, these efforts should draw on the lessons learned from similar types of integration, such as adding FP to postabortion and postpartum care.**

The importance of microbicides has been mentioned above, and CTR fills an important need by keeping an RH perspective in microbicide work while looking holistically at women's needs. As one respondent explained, "Sometimes in behavioral work, even though the focus is on microbicides, the studies on negotiation have broader applicability."

CAPACITY BUILDING

The current CTR project predated development of the Results Framework at USAID, so it does not have IRs against which progress in capacity building is specifically measured. Nevertheless, capacity building historically has been included in nearly all research, dissemination, and research use activities implemented under CTR. In addition, specific capacity-building activities, such as assisting developing country partners and programs; and design, conduct, and use of the results of contraceptive and RH research, have been carried out through CTR. The most important of these include the following:

- a qualitative research methods manual was published (widely used in academic programs and to support field research);
- scientific writing, operations research, and monitoring and evaluation workshops were conducted (several countries);
- a research ethics curriculum was published;
- training courses and workshops were conducted in several countries;
- good clinical practices were monitored (South Africa and Kenya); and
- contraceptive technology updates/Maximizing Access and Quality (MAQ) Exchanges (global) were conducted (accounts for about 10 percent of the work done through the CTR agreement).

In addition to these special activities, research capacity has been strengthened in several developing countries through the participation of host-country researchers in successful clinical studies. For example, at the Cameroon site, where CTR conducted microbicide studies, an emphasis of the research team was transferring knowledge and skills regarding research methods, good clinical practices, ethics, informed consent, research management and data analysis, and reporting to local researchers. As a result, the Cameroon site is now recognized as having outstanding clinical research capability.

Many USAID-funded CAs and contractors work at the service delivery level to increase the capacity of local providers. In order to avoid duplication of effort, in the follow-on project, **CTR should build on its comparative advantage by focusing on**

- **increasing the number of developing country researchers and local staff qualified to design, implement, analyze, and use the results of contraceptive and microbicide research; and**
- **identifying and developing clinical trials sites.**

Over the next 10–15 years, having sufficient qualified researchers and clinical trial sites is critical to winning the war against AIDS, tuberculosis, and malaria in addition to continuing contraceptive research. While this is a mammoth task, CTR is uniquely qualified to undertake this task because over the past eight years CTR has

- strengthened its core of world-class experts in sexual and RH research,
- diversified its scientific skills into behavioral and qualitative research areas, and
- set the global standard for clinical research methodology and reporting.

Strengthening researcher capability and building clinical research site capacity in developing countries should be the focus of CTR's capacity-building efforts in the follow-on project. Moreover, this task must be accomplished as expeditiously as possible, for as one respondent noted, "The flood of clinical trials is just beginning."

Staff Development

In the current project, CTR has made an excellent start at addressing the overwhelming need for locally qualified researchers through

- the production of several excellent learning materials (e.g., a qualitative research methods manual and a research ethics curriculum);
- pairing of and mentoring country office researchers and staff involved in clinical trials and other research areas (behavioral, economic, and programmatic studies); and
- ensuring that field-based researchers and other staff operate at professional levels consistent with good research practices and good clinical practices.

In addition, as mentioned above, because of the improved knowledge and skills of researchers at the clinical trial site in Cameroon, it is now considered a world-class clinical research site for microbicide and potentially other types of studies (e.g., vaccine testing, antiretroviral interventions, and numerous other safety, acceptability, and costing studies). During the remainder of the current CTR agreement and in the follow-on project, **sufficient resources should be made available to**

- **formalize the process of transferring the required knowledge and skills needed to design, conduct, analyze, and report high-quality clinical studies, including how to develop and maintain study sites (this may involve developing additional competency-based learning materials and curricular components to supplement existing ones);**

- **develop and field test these new competency-based learning materials;**
- **develop a group of qualified international and developing country trainers; and**
- **expand the impact of the capability of developing country researchers at designated sites in Africa and Asia as expeditiously as possible.**

Study Site Identification and Development

Estimates of the number of participants needed in the proposed clinical studies to evaluate microbicides and other HIV/AIDS interventions greatly exceed the current capacity. While identification and selection of clinical sites is challenging, FHI is the organization best qualified to do this because it has already been successful, is part of the HIV prevention trials network, has potential access to more than 40 IMPACT country offices, and is well accepted internationally as being excellent partners and collaborators.

To be selected, a research site must meet rigorous requirements to implement the protocol (i.e., have qualified field investigators, trained staff, and adequate access to appropriate study populations) and staff members must have an interest in participating as a research site. In addition, for USAID-sponsored research studies, Missions should concur with having the research conducted in the countries selected. Because Mission staff members often have limited interest in research, even clinical trials of potential microbicides, this can be a major obstacle in developing new clinical trial sites.⁶

In 2002, CTR began a concerted effort to identify and develop potential sites. Currently, CTR researchers are working with FITS and field office staff to

- identify potential sites,
- foster relations with key stakeholders in countries of interest, and
- select site investigators who are familiar with the in-country approval process.

To expedite this process **CTR should**

- **take the lead in conducting a summit meeting comprised of all the vaginal microbicide research stakeholders (e.g., NIH, CDC, CONRAD, the Population Council, and WHO) to develop a strategy and action plan for meeting the needs for clinical sites and study participants as presently envisioned;**
- **evaluate the potential for developing sites through IMPACT's network of more than 40 country offices; and**
- **investigate the potential of using WHO collaborating centers as trial sites.**

⁶ Contrary to the statement in the self-assessment, USAID is not opposed to having clinical trials conducted in non-joint programming countries (e.g., Brazil, Mexico, or Thailand).

USAID Mission willingness to approve core-funded research is an issue that USAID/Washington needs to address. Given that developing a vaginal microbicide is considered critical to providing women throughout the world with some control over their future, it is difficult to understand a Mission's refusal to participate. This issue may surface again when a potential vaccine becomes available for testing.

RESEARCH TO PRACTICE

Although in its infancy, the RtoP Initiative is a necessary addition to CTR's portfolio and to that of the follow-on project. Respondents for this assessment were clear in their message: USAID-supported research projects should no longer be able to justify their funding based on publishing in journals or presenting at professional meetings. They must now translate and promote best practices for impact. "One would like to see more direct advocacy work around the research that is now happening." "There needs to be more deliberate efforts to get results utilized." "FHI is not the Academy; [they] need to place more emphasis on research to practice not just research to publish."

Several respondents expanded on this theme and expressed the need for a new procurement focused only on the use of research findings, noting that it is critical and that it should be bureauwide and involve all CAs, and that a research to practice or impact project would help all CAs "get their research into practice." **USAID should consider creating a new procurement that would expressly facilitate the use of best practices.**

There are several forces operating to encourage this transition from publication of research findings as sufficient to the requirement for use. Policymakers and practitioners are seeking evidence-based findings to guide their public health efforts. Stagnant or diminishing resources for RH have heightened the expectation that expenditures show results. In addition, health and development work has matured to the point that there is a significant body of knowledge, which now needs to be put into practice. Yet a general endorsement of applying research findings to health and development practices is not enough. Specific mechanisms must be built into the follow-on CTR project to facilitate successful implementation of this objective.

The CTR Request for Application will need to clarify the new project's responsibilities concerning this objective. Questions concerning whether it will be evaluated and judged on research to dissemination, policy change, curriculum revision training, changing provider practices, client behavior change, or health impact will need to be addressed. While research organizations can facilitate transfer of best practices to health providers, it remains the task of service delivery, training, and communication organizations to ensure that these best practices are implemented. One respondent related that FHI is not the best organization to set up or evaluate training, and that strong CAs with service delivery and behavior change communication capabilities already exist.

Putting this research to practice linkage into operation will require resources. Many of those interviewed believed that without funding, uptake of even highly significant research findings would occur slowly or not at all. (See Funding Mechanisms section below.) There are several possible scenarios for funding these partnerships. Each research study could have designated funds for use that would be carried out by a group of implementing partners. This would facilitate input from a policy, service delivery, and/or training (and potentially provider and user) perspective early in the process of defining

the research question. Another approach would be to establish a discrete use fund for the next CTR project. Once research results were identified as warranting expansion of impact or not, a request for application outlining use parameters would be developed. Implementing organizations would then submit proposals with budgets, and a TAC or other quasi-independent body could be involved in selecting the grantees.

The issue of undertaking research to practice is not unique to CTR, and is currently being discussed throughout the RH and development community through meetings, consultations, and publications. New initiatives, such as Implementing Best Practices (IBP), Getting Research into Policy and Practice (GRIPP), Turning Research into Practice (TRIP), and Essential Care Practice Guidelines (ECPG) are joining the MAQ Initiative in pushing the issue of use to the forefront. USAID and research and service delivery organizations should discuss the best mechanism to increase use. In the future, CTR should continue to learn from and work collaboratively with other global efforts in this area.

Thirty years of in-service medical training in the developing world have resulted in a continuing need for such training. Although perceived as more complex and time consuming to institutionalize, **the future research to practice should include linkages to preservice education and training through appropriate partnerships.** Moreover, in the follow-on project, CTR should also focus on professional societies as conduits for research dissemination and training in best practices. The emphases on public/private partnerships and decentralization require new strategies for accessing providers and encouraging continuing education and training. In addition, professional societies provide an entry to the health workforce that is not available solely through the MOH or NGOs.

The facilitating aspects of field presence for research uptake have been alluded to throughout this report but need reemphasis. In-country research that has involved local decision-makers from the outset will have more influence and may be easier to add to the mainstream. The increased field presence recommended for the follow-on project should assist researchers in asking appropriate questions and should accelerate the research to practice process.

Information dissemination, although not sufficient, is a necessary component of research to practice. One of the dissemination mechanisms that CTR has used is its quarterly publication, *Network*. Several of those interviewed thought that while *Network* was an important source of information, it promoted FHI too heavily. Others stated that it would be important to work with the INFO Project to see if offerings from USAID-funded research projects could be combined into one publication. In the follow-on project, ***Network* should continue to be produced, but less expensive production and dissemination options should be explored, and the content should cover important research findings from other, non-FHI sources.**

MONITORING AND EVALUATION

The current CTR cooperative agreement has focused on output measurements, such as number of studies conducted, number of peer-reviewed publications, and number of workshops. For example, contraceptive technology update modules were developed and more than 15,000 were distributed. FHI has examined how many were trained with these modules, and there is some information on use, such as the modules being the basis of the

FP curriculum in medical schools in Egypt. There was, however, limited follow up on the modules, and to date there has not been a rigorous evaluation of their impact. In a case such as this, a more thorough evaluation should have been conducted at an earlier stage to make sure such a large investment of time and resources would be worthwhile.

With the current focus and attention placed on turning research into practice, it is important that the follow-on project contain increased emphasis on outcome and effectiveness measures. This will help to ensure that the next CTR project is guided by the principles of turning research into practice. Moreover, documenting, measuring, and analyzing the research and use process will provide valuable insights and lessons on improving the process of translating research into practice and impact. In the next project, **staff from FHI, the Population Council, and USAID (RTU and SDI divisions) should develop a core set of indicators for measuring both the determinants and extent of use of research findings.** This should build on existing efforts, such as the toolkit on turning research into practice being developed with WHO and the FRONTIERS' evaluation manual, *Evaluating Operations Research Utilization: Guidelines for Assessing Process and Impact*.

Different types of research will lead to different types of use, and this needs to be considered when determining appropriate indicators. Use will also depend on study findings. For example, in the case of nonoxynol-9, rather than use of findings following an expansion of impact process, it was the opposite. Whether findings are positive or negative, it is essential that important lessons be shared and acted upon, and researchers can have a key facilitating role in ensuring that this happens. The monitoring and evaluation plan needs to recognize that turning research findings into policy and programmatic changes can be a lengthy process. Therefore, indicators and expectations need to remain realistic and allow adequate time to fully assess change. **The next CTR award should include increased emphasis on outcome and impact measures. In addition, there should be measurement of the research and use process to develop guidelines for maximizing turning research into practice.**

FUNDING MECHANISMS

The follow-on project should continue as a cooperative agreement, allowing flexibility in interpretation and implementation, with substantial involvement by USAID/Washington. It is important that there be sufficient core funding. Over the years, CTR's core funding plus a supportive management team at USAID have allowed FHI to attract considerable additional research funding from NIH, private foundations, and the Office of HIV/AIDS (USAID/GH/OHA) for clinical research. Such leveraging is crucial since Missions are generally not interested in funding clinical research with field support, and clinical trials are extremely costly. In fact, it will cost an estimated additional \$12–38 million per year for several years, just to conduct the planned phase 2/3 studies alone. These funds will need to be garnered from other sources (e.g., USAID/GH/OHA, CONRAD's GMP, or NIH) using CTR core funds as seed money. To avoid negative impacts on CTR's normal research agenda, **the present level of core funding should be maintained or increased for the follow-on project.**

By all accounts, it may take more than a decade for the microbicides currently in the pipeline (even if rationalized to a few of the best leads) to yield products that will offer a high degree of protection against STIs while at the same time preventing pregnancy.

Dismantling the existing research infrastructure resident in the CTR project and thus derailing further development and introduction of these products would set the public health agenda back by a decade. For this reason, **USAID should continue its support of current CTR contraceptive and microbicide research in the pipeline by awarding a 10-year, noncompetitively bid cooperative agreement to FHI when the present project ends in 2005.**

The development of vertical programming in HIV/AIDS work is troubling but understandable given the original targeting of high-risk groups and the new emphasis on antiretroviral therapy that brings with it a biomedical subspecialist mentality. Clearly, a case management approach is insufficient to improve population health. Moreover, increased amounts of HIV/AIDS funding relative to that for other RH conditions have led to less integrated programming.

Benefiting from nearly three decades of CTR funding, FHI has become one of only a few organizations having the breadth and expertise to conduct high-quality clinical and behavioral RH research in the developing world. Many of those interviewed expressed support for continuing to infuse this RH capacity and perspective into HIV/AIDS programs and research:

“Maintain an RH focus; too much of HIV/AIDS work is vertical, re-creating the same problems we used to have for FP. VCT should be embedded into existing programs from the outset, not set up as a series of freestanding testing sites.” “FHI [CTR] is well placed to look at microbicides with an FP perspective—how do you handle counseling, dual protection issues? FHI has done a lot of interesting work in integration and this will continue to be very important.” “Where’s the M in MTCT?”

To promote a reproductive health approach, **in the follow-on CTR project, the research mandate should be broadened to allow for funding and research requests from all three offices in the Bureau for Global Health (GH)—Population and Reproductive Health (GH/PRH), HIV/AIDS (GH/OHA), and Health, Infectious Diseases and Nutrition (GH/HIDN).** Such a funding mechanism would allow CTR to bring its contraceptive research (clinical, behavioral, economic, and programmatic) and RH focus to bear on the current major public health problems, promoting integrated solutions to complex problems. This is especially important given the artificial program boundaries that vertical HIV/AIDS funding is creating in the field. The health and development paradigm shifted to RH nearly a decade ago for a reason. Clients are not mere repositories of distinct disease entities or organ systems, but rather individuals with reproductive goals and aspirations. Because the follow-on CTR project should embrace this reality and facilitate addressing health issues through an RH health framework, **staff from GH/OHA and GH/HIDN should be members of the follow-on project design team.**

Field support will continue to be an important source of funding to answer local research questions as well as for country-level programs. Increasing field presence in the follow-on CTR project should facilitate Mission funding. It is also important that funding for use be built into project core funds. This is especially relevant should the follow-on project mandate a research to practice approach that goes beyond dissemination and policy change. (See above section, Research to Practice.) To facilitate this, in the next project,

CTR will need to collaborate with service delivery, training, and communication CAs, and together develop monitoring and evaluation systems that can report on changing provider practices and client behaviors.

APPENDICES

- A. SCOPE OF WORK**
- B. PERSONS CONTACTED**
- C. KENYA TRIP REPORT**
- D. REFERENCES**

APPENDIX A

SCOPE OF WORK (from USAID)

SCOPE OF WORK

Assessment of the Contraceptive Technology Research Project: Reviewing Progress and Results, and Making Recommendations for Future USAID Action

I. Background

The Contraceptive Technology Research Project (CTR, project no. 936-3079) is being implemented by Family Health International (FHI) through a cooperative agreement with USAID (CCP-A-00-95-00022-02). This is a ten-year project that was authorized on May 4, 1995 with a PACD of September 30, 2005. The five-year cooperative agreement began on August 31, 1995 and was extended for the second five-year period to end on August 30, 2005. The project was authorized at a funding level of \$187,000,000 for the ten-year period and \$122,151,433 have been obligated to date into the cooperative agreement.

This project follows two earlier contraceptive technology projects implemented by FHI: 932-0537 and 936-3041. Since 1971, FHI has carried out a program of research, technical assistance and information dissemination to expand contraceptive choices and improve understanding of family planning and reproductive health (FP/RH) needs of men and women in more than 50 countries. With USAID support, FHI has developed its capacity and reputation as an international leader in the field of contraceptive technology and family planning research. Over the last 30 years, projects with FHI have documented the comparative safety, efficacy and acceptability in different developing country settings of methods such as minilap and laparoscopic sterilization, NORPLANT, copper IUDs, low-dose combined and progestin-only oral contraceptives, and various barrier contraceptives, including condoms.

The CTR project contributes specifically to two of the Global Health Bureau Strategic Objectives. These are SO1 – increased use by men and women of voluntary practices that lead to reduced fertility, and SO4 – increased use of proven interventions to reduce HIV/STI transmission. The Intermediate Results that are addressed include IR 1.1 – new and improved technologies for contraceptive methods and family planning programs, and IR 4.1 – increased quality, availability, and demand for information and services to change sexual risk behaviors and cultural norms in order to reduce transmission of HIV. In addition, the CTR project responds to the Biomedical and Operations Research Results Frameworks (Attachment 1a and b) developed by the RTU Division of OPRH.

The overall goal of the cooperative agreement is to increase the means available to developing country couples to achieve their desired family size. The specific objectives are to develop and introduce a range of safe, effective, and acceptable methods of family planning, and more recently disease prevention technologies; and to strengthen the capacity of developing country researchers and to improve provider practices. Illustrative activities include:

1. Developing and testing new contraceptive methods and microbicides and providing the documentation for regulatory approval of these methods;

2. Conducting clinical trials and epidemiological studies to evaluate the safety and efficacy of various contraceptive methods and microbicides under different conditions;
3. Assessing the acceptability and impact on users and programs of various contraceptive methods and microbicides;
4. Developing and testing tools and strategies to increase the availability and choice of contraceptive methods and microbicides in family planning and reproductive health programs;
5. Developing and testing methods to improve provider practices;
6. Carrying out surveillance and testing of contraceptive commodities to ensure product quality;
7. Building the research capacity of overseas providers;
8. Collecting, analyzing and disseminating research findings.

In the current project, FHI has emphasized the development and testing of new barrier methods, both physical and chemical (microbicides), for the prevention of STDs/HIV transmission, as well as pregnancy prevention. In addition, the CTR has supported a large volume of work on vasectomy. FHI works closely with the CONRAD program and the Population Council's FRONTIERS project to coordinate and implement program research, both as a partner within the FRONTIERS project and through the CTR project.

II. Purpose of the Assessment

The purpose of this assignment is to assess the performance and results of the CTR project and provide guidance to USAID for the design of a follow-on project. Specifically, the assessment team would be expected to:

- Assess the performance of the CTR project relative to the goals and objectives of the cooperative agreement;
- Assess the results of CTR's research findings and capacity building activities on family planning and reproductive health programs worldwide and ;
- Provide guidance to USAID on the scope of a future project and mechanisms of funding.

The team will spend 50 percent of its efforts on assessing performance and results (first two bullets combined) and 50 percent on providing guidance on future direction for a follow-on project (third bullet).

III. Existing Performance Information Sources

For this assessment, the existing sources of information on the performance of CTR include the annual workplans and reports, the interim reports, annual results reviews, annual TAG reports and periodic special reports, strategy documents, management reviews, and the report from the external evaluation (1994). These documents detail the successes of the project and issues related to implementation and decisions made to resolve them. Additional information can be acquired by the Assessment team through interviews with CTR and USAID/W and Mission staff, other USAID cooperating agencies, other stakeholders and field visits. The suggested relevant documents are listed below, and suggested lists of interviewees are attached.

IV. Questions to be Addressed

The following are specific questions to be addressed by the team. Additional questions and issues may be added at the team's discretion. In all instances, the team should ask the interviewees what they consider the strengths and weaknesses of the CTR FHI program. The assessment team, with RTU staff, should prioritize the questions listed below to increase efficiency of the process.

A. Research Quality and Impact

1. How well does the CTR research agenda contribute to the overall goals and objectives of RTU's biomedical and operations research frameworks? What was the process by which the agenda was identified? How well does FHI work with other research CAs to implement the agenda?
2. What is FHI's view of its mandate? Do they have a strategic vision? How do they prioritize their broad range of activities?
3. To what extent has FHI successfully completed the Scope of Work of the CTR throughout the duration of the period covered by the assessment? What unexpected results, positive or negative, have been achieved that were not originally projected in the Scope of Work?
4. What have been the results of FHI's research on FP/RH programs in developing countries? What is the process that FHI follows to ensure utilization of research results and how well is the process functioning? What indicators exist to assess FHI's dissemination of the latest contraceptive technology research findings? How well does FHI work with other projects, including research and service delivery CAs, HIV/AIDS CAs to implement studies and utilize research findings? Please identify specific examples of utilization.
5. In the past few years, strengthening research and management skills of investigators, institutions and programs in developing countries has not been emphasized as much as it was in previous agreements? What should be done in the future regarding this issue? Should the current emphasis on improving provider practices continue to take precedence over capacity building?
6. Review and comment on the work of the Quality Assurance/Product Surveillance Unit. To what degree does this unit benefit from, and provide benefit to other parts of the organization within the cooperative agreement?

B. Management and Financial Issues

1. How does the current management structure and administrative system enhance or inhibit the implementation of the cooperative agreement? Are project resources and activities being allocated to maximize efficiency and effectiveness? In what ways, if any, should the structure and management processes be changed?
2. How efficient is FHI in developing research projects? How efficient is the approval process for implementing new studies? Is the time from concept development to field implementation reasonable? What, if any, process and management changes are needed to improve efficiency?

3. How successful has FHI been in recruiting and retaining staff well-suited to achieving the objectives of the cooperative agreement? Are there areas where additional staff is needed, or where a reduction in staff would be appropriate? How well does FHI use contract staff? Should there be a greater emphasis on short-term staff?
4. How does the funding allocation within FHI relate to the objectives of the cooperative agreement? How appropriate are the decisions that have been made when budgets had to be reduced or increased?
5. To what degree have USAID funds been used as seed money to attract other funds? What type of changes should occur, if any, to facilitate this process?
6. What are the strengths and weaknesses of the relationship between FHI and USAID? What is FHI's assessment of USAID's administration of this cooperative agreement and vice-versa?

C. Portfolio Assessment

1. How does the CTR portfolio of potential products and leads relate to the portfolios of other CAs (CONRAD, The Population Council, PATH and WHO) that are also working on contraceptives and microbicides? What are the advantages and/or disadvantages for USAID in having three primary CAs working in contraceptive and microbicide research and development? What overall strategic recommendations can be made for USAID in this regard?
2. Similarly, how does the program research within CTR compare with the portfolio of FRONTIERS? What are the advantages and/or disadvantages for USAID in having two CAs working in the field of operations and program research? (The Expanding Contraceptive Choice Program within the Population Council's Program Grant was dropped in FY02). What overall strategic recommendations can be made for USAID in this regard?
3. What are appropriate levels of funding for the various research components?

D. Future Directions

1. The CTR project is a combination of biomedical and program research, together with product surveillance capacity, and a variety of integrated activities (e.g. information dissemination, statistical support, data management etc.). What are the advantages and/or disadvantages of having multiple capabilities within the same project? Does such a combination have any financial and programmatic benefit for USAID? Would the team recommend a similar combination for the future or propose some changes? Are there any parts of the current program that would be best suited for competition?
2. Are major changes needed to the overall objectives of the current program? If so, in which areas, and to what extent?
3. What are the future research initiatives that FHI believes should receive priority attention, and what, if any, barriers to progress will need to be addressed within a new program? What is the team's assessment of these priorities and barriers to progress?
4. In this agreement, to what extent does the design hold FHI accountable for measuring and reporting results of research? What have been the successes?

What are the barriers to utilization of research results and how can they be overcome?

V. Methodology

1. Self-assessment: USAID will request FHI to prepare a self-assessment of the CTR Project, based largely on the questions above, and the report will be provided to the Team as part of the background materials.

2. Assignment Preparation:

- Prior to arrival in Washington D.C., the assessment team will further refine and prioritize the key questions to be addressed in the interviews. The team will also develop the general methodology to be used in the assessment in collaboration with the NEP (New Entry Professional).
- The assessment team will initially meet with the USAID staff (RTU Division) to be briefed on the CTR/FHI Cooperative Agreement and the activities of CTR. The team will then develop an overall final assignment workplan, defining the responsibilities of individual team members, agreeing on a schedule for specific activities, and addressing other operational and logistical issues as needed.

3. Background Documents/Materials: The following documents will be provided to the Assessment Team. Other documents may be added or requested as needed.

- Last two management review reports
- Cooperative Agreement CCp-A-00-95-00022-02
- Last Evaluation Report (1994)
- Annual Workplans, July 2002-June 2003 and July 2003-June 2004 (earlier years available upon request)
- Interim Reports July 2002 to June 2003
- Results Review documents for FY 2003
- Minutes from April 28 meeting of Office of Population and Reproductive Health Senior Staff to discuss follow-on options to CTR/FHI.
- Minutes from May 2003 TAC
- Self-assessment report from FHI
- Succinct description of other biomedical and operations/program research implemented by other USAID Cooperating Agencies (CONRAD, FRONTIERS, Population Council Program Grant, PATH, WHO/HRP)
- Report of the 2003 Assessment of the Center for Biomedical Research, Population Council.
- Summary reports on implementing TAC recommendations
- Significant publications such as
 - Latex Condom Monograph
 - Qualitative Research Methods Manual

- Research Ethics Curriculum
- Issues of *Network*

4. *Interviews*: In continuing consultation with the RTU Division, we anticipate that the Assessment Team will extensively interview selected RTU and other staff at USAID, FHI, and other research and development organizations that are working on biomedical and operations/program research (e.g., CONRAD, NICHD, PATH, The Population Council, WHO/HRP). Other stakeholders will also be interviewed and might include CAs such as JHPIEGO and EngenderHealth, as well as other researchers, advocates, donors, or other parties chosen by the assessment team.

As stated above, the team will prepare the general interview questions prior to arrival in Washington D.C. in coordination with a staff member from USAID (the NEP). USAID will send out the interview and survey questions to the respective interviewees prior to the interviews. POPTECH will follow up by arranging and scheduling all of the interviews.

In most cases, it is expected that interviews with people who are USAID or FHI staff will be conducted in person with the entire assessment team present at the same time. Interviews with people who are not USAID or FHI staff will probably be conducted by telephone, again with the entire assessment team conducting the interview as a group.

5. *Field Visits*: The assessment team is tentatively scheduled to travel to Kenya to visit ongoing CTR subprojects and assess the quality of research, stakeholder involvement, and potential for utilization and scale up of results of the research. The Team will also have the opportunity to conduct interviews with key informants to assess the extent to which results of past research conducted by CTR/FHI have been incorporated into programs within Kenya and other countries within the region and elsewhere in the world. The reasons for selection are: high level of resources invested in research; multiplicity of research studies implemented in country; support for research by local Mission; and planned efforts to take research results to practice. FHI will be responsible for logistical planning while the team is in Kenya and North Carolina.

In addition, FHI is planning to undertake detailed evaluations of CTR's work in several countries over the next two years. Information that FHI gathers on any country evaluated prior to carrying out this assignment will be made available to the team.

VI. Deliverables

1. *Report*: After collecting the information sought, the assessment team will analyze and synthesize conclusions that address the key questions above. The team will then prepare a report (about 30 pages, plus attachments) that describes methods used in the assessment, and presents the conclusions and recommendations of the team regarding the key questions, along with an

executive summary. The report will be written as one report, with two parts (assessment and future direction) and will be external. The report will be edited by POPTECH.

2. Debriefings: The Assessment Team will provide separate debriefings to both USAID and FHI in Washington D.C.

VII. Team Composition

The Assessment Team must be qualified to make a wide range of possible recommendations, and be sufficiently respected and influential that its recommendations will be considered to be authoritative. The Agency does not want a review that only confirms preconceived conclusions or views held by USAID staff or FHI staff.

It is expected that four POPTECH consultants with complementary knowledge in this field will constitute the Assessment team. In addition, a USAID staff member, a NEP, who is not involved in the daily management and decision-making process for the FHI/CTR Project, will be available to work with the Assessment Team as an observing adjunct member. The NEP will coordinate and help develop the methodology, questions, and survey instrument, attend meetings/focus groups, and participate in site visits, etc. The consultants, as a team, should have expertise in the following areas:

- Expertise in contraceptive, reproductive health, and HIV prevention technologies
- Knowledge of the product needs for family planning and HIV prevention programs in developing countries
- Experience in provision of family planning and other reproductive health services in developing countries
- Experience in the development of reproductive health products that includes biomedical aspects, regulatory approval, development of business plans, partnerships and other alliances, and agreements for manufacturing, licensing and marketing
- Knowledge of operations and program research and service delivery issues related to reproductive health technologies in developing countries
- Knowledge of issues related to information dissemination and utilization of research for program improvement
- Developing country experience.

Senior and possible retired persons with careers related to contraceptive or microbicide research and development, and/or reproductive health care in developing countries, might be good candidates to consider. Ability to work as a team member, evaluate and synthesize information quickly, make clear and well-founded recommendations, and contribute to the written report and debriefings is essential. Careful judgment should be used to recruit consultants who are knowledgeable and highly respected in this field, but are as unbiased as possible about this area of research and its future directions.

It is estimated that up to seven weeks of effort will be required for each of the consultants on the Assessment Team, and possibly an additional week for the team leader. Some of the work will be conducted at home prior to the teams' arrival in Washington DC. This

will include prioritizing the interview questions. **The questions should be submitted to POPTECH and USAID by July 25, 2003.**

VIII. Scheduling and logistics

The team will be expected to prioritize and compile the questions in the SOW by July 25 to form general interview questions that will be sent out to the interviewees via email prior to the actual interviews. The team will work from home and the USAID NEP will coordinate this effort. The team will be given approximately four days of LOE to do this at their discretion during the weeks of July 7 – July 21. USAID will send out the interview questions to the interviewees and POPTECH will schedule all of the interviews.

It is anticipated that 2-3 trips to Washington, 1 trip to North Carolina, 1 trip to Kenya and possibly one additional site visit (to be determined) will be required to carry out the assignment and conduct the debriefings.

APPENDIX B

PERSONS CONTACTED

PERSONS CONTACTED

U. S. Agency for International Development (USAID), Washington, D.C.

Lee Claypool
Victoria Ellis
Nomi Fuchs
Sarah Harbison
Carl Hawkins
Steve Hawkins
Jerry Jennings
Mihira Karra
Amy Leonard
Shawn Malarcher
Judy Manning
Margaret Neuse
Scott Radloff
Mark Rilling
Harris Soloman
Jeffrey Spieler
Ellen Starbird
Dana Vogel

USAID Missions

Mary Ann Abeyta-Behnke, Ethiopia
Jocelyne Andrianadana, Madagascar
Amy Cunningham, Uganda
Sheila Macharia, Kenya
Michael Strong, Kenya
Melinda Wilson, South Africa

AMKENI

Job Obwaka

Brookebond Central Hospital, Kenya

Walter Odonde

Brookebond Dispensaries, Kenya

Raphael Kamin
Race Ochogo

Brookebond, Ltd Tea Estate, Kenya

John Cheruiyot

CONRAD Program

Marianne Callahan
Douglas Colvard
Henry Gabelnik
Christine Mauck

Custom Services International

Lillie Thomas

DELIVER Project, JSI

Richard Owens

Lois Tod-Hunter

EngenderHealth

David Adriance (Kenya Office)

Mark Barone

Roy Jacobstein

Family Health International (FHI), North Carolina

Eli Carter

Ward Cates

Rosalie Dominik

Laneta Dorflinger

David Grimes

David Hubacher

Barbara Janowitz

Joanne Lewis

Susan MacIntyre

Kate MacQueen

Tara Nutley

Beth Raymond

Heidi Reynolds

Beth Robinson

Al Siemans

John Stanback

Matthew Tiedeman

Frank Webb

Mike Welsh

Gary West

FHI/CTR Kenya

Violet Bukusi

Dorcas Kungu

Maureen Kuyoh

Jennifer Liku

Ndugga Maggwa

Cathy Toroitich-Ruto

FHI/CTR Kenya Field Sites**Brooke Bond Condom Choice Study Team**

Samson Barwecho

Peter Khacmba

David Kimuge

Zablon Omungo
Bernard Onyango

Nandi Hills Tea Growers Association
Simon Davies, Eastern Produce Kenya Ltd.
Joseph Muga, Chemomi Tea Estate
Luke Osire, Kapchorua Tea Estate

FHI/CTR Technical Advisory Committee

Sharon Hillier, University of Pittsburgh
Helen Rees, University of Witwatersrand
S. K. Sinei, UHMC, Kenya
Robert Spirtas, NICHD
James Trussell, Princeton University

IMPACT Project (FHI), Kenya

John McWilliam
Peter Mwarogo

Global Campaign for Microbicides

Lori Heise

GTZ Kenya

Mark Ayallo

Horizons Program, Population Council

Andy Fisher

IntraHealth International, Inc.

Alfredo Fort
David Killian
Rose Wahome (Kenya Office)

JHPIEGO

Sue Griffey
Pamela Lynam (Kenya Office)

Kenya Obstetrical and Gynaecological Society

Joseph Karanja

Ministry of Health, Department of Reproductive Health, Kenya

Josephine Kibaru

Ministry of Health, National AIDS and STD Control Program (NASCOP), Kenya

Kenneth Chebet

National Institute of Child Health and Human Development (NICHD)

Gabe Bialy

Packard Foundation

Elmar “Tom” Vinh Thomas

The Population Council

Ian Askew (Kenya Office)

Martha Brady

Jim Foreit

Elof Johansson

Regine Sitruk-Ware

John Townsend

Program for Appropriate Technologies in Health (PATH)

Glenn Austin

Michelle Folsom (Kenya Office)

Michael Free

Rikka Transgrud (Kenya Office)

Reproductive Health Outlook (RHO), PATH

Dennis Wallace

University of Rochester Medical Center

Eric Schaff

U. S. Food and Drug Administration (FDA)

Donald Marlowe

University of Nairobi, Department of Obstetrics/Gynaecology

Eunice Cheserem

Western Province, Kenya

Alan Gohole

Cornelius Kondo

Fredrick Nyumba

Dorothy Odondi

World Health Organization (WHO)

Tim Farley

David Griffen

Paul Van Look

Iqbal Shah

Kirsten Vogelsong

YouthNet

Nancy Williamson

APPENDIX C

KENYA TRIP REPORT (from FHI)

Kenya Trip Report

SITE(s): Nairobi, Kericho, Kisumu, Nandi Hills and Vihiga, Kenya

DATE(s): October 4-13, 2003

TRAVELER(s): Consultants (Claudia Morrissey Colon, Gordon Duncan, Noel McIntosh and Julie Solo)

EXECUTIVE SUMMARY

Over a seven-day period the four members of the CTR assessment team: 1) reviewed the CTR/Nairobi office portfolio of research; 2) conducted meetings with staff from CTR/Nairobi and agencies with which this regional office collaborates or partners, including a briefing with the US/Kenya mission; and 3) made field visits to assess CTR/Nairobi staff's work. In all areas, the team found CTR/Nairobi staff perform at a high level, are respected for the quality of their work and for their responsiveness, flexibility and collegiality. Several recommendations for CRT/Nairobi, FHI/NC and USAID/DC were made.

PRINCIPAL CONTACTS

For a complete listing of principal contacts, please see attached CTR Assessment Agenda (**Appendix A**).

PURPOSE

The purpose of the trip was to conduct a site visit to FHI/Nairobi, Kenya (East and Southern Africa Regional Office) to assess their implementation support of the Contraceptive Technology and Family Planning Research (CTR) Cooperative Agreement with USAID.

ACTIVITIES AND ACCOMPLISHMENTS

Over a seven-day period the four members of the CTR assessment team participated in three types of activities:

1. Reviewed the current and recently completed portfolio of research and program activities with CTR/Nairobi and selected IMPACT project staff.
2. Met with agencies and organizations with which CTR/Nairobi collaborates or partners and had a briefing with the USAID/Kenya mission.
3. Made visits to Kericho, Kisumu, Nandi Hills and Vihiga to meet with field staff and partners of ongoing CTR/Nairobi-supported activities.

Findings

1. The assessment team (A team) was impressed by the extent and quality of the research and program activities completed by CTR/Nairobi during the past few years. In particular, the studies documenting the potential for successfully integrating FP into VCT centers, evaluation of the cascade method of training, use of the pregnancy checklist, and re-introduction of the IUCD in Kenya were well done and have served to guide MOH/Kenya in revising FP guidelines and prioritizing interventions for the future.
2. During the past few years, CTR/Nairobi has collaborated or partnered with a wide range of agencies and organizations. In all cases, CTR/Nairobi is viewed as a competent, highly qualified and valued collaborator or partner that is easy to work with. Within the international technical assistance community, including the MOH and USAID, CTR/Nairobi has established an excellent reputation. By working together with many organizations, CTR/Nairobi has become a lead agency in helping the MOH coordinate efforts to improve the quality of and access to FP activities. In addition, the working relationship with the USAID/Kenya mission is excellent. Moreover, the mission is very satisfied with the responsiveness of CTR/Nairobi in assisting the mission carry out its reproductive health strategy. Concern, however, was raised by the mission that while FHI's involvement in large-scale HIV/AIDS research studies (e.g., microbicide trials) is important globally, CTR/Nairobi should continue to focus its work on supporting local (Kenya) needs. Mission staff also expressed the need for their active involvement with USAID/DC in the design of any follow-on CTR project.

3. In the field, CTR/Nairobi staff collaborate and partner with various agencies and organizations in order to successfully conduct studies and implement activities. While the A team was only able to visit study sites in the Western Province (Kericho, Kisumu, Nandi Hills and Vihiga), in these places CTR/Nairobi participation and technical expertise were highly regarded. CTR/Nairobi also has excellent relations with the AMKENI project, a USAID-supported bilateral project of which CTR/Nairobi is a partner, both in the field and in Nairobi. Moreover, GTZ with whom CTR/Nairobi is collaborating on projects aimed at preventing unwanted pregnancies and HIV/AIDS in adolescents in Vihiga is very pleased with the technical assistance provided by CTR/Nairobi and their responsiveness and flexibility.
4. During the past few years the CTR/Nairobi office has undergone considerable growth not only in size and funding, but also in expanding the technical capabilities of existing staff to design, implement and analyze high-quality research studies. FHI/NC has actively supported and contributed to this process through the “twinning” process (i.e., linking CTR/Nairobi staff with FHI/NC counterparts). CTR/Nairobi senior staff expressed the need to continue this process. There also is a need for additional technical capacity (e.g., in biostatistics and data analysis). This could be accomplished either by increasing the knowledge and skills of existing staff and/or bringing in new technical staff. (USAID Kenya seconded the need for CTR/Nairobi to have additional technical capacity, including having additional technical staff.)

Recommendations

1. CTR/Nairobi should consider transferring research ethics information and training skills to medical and nursing faculty so that they can provide this training to other faculty and local researchers.
2. CTR/Nairobi should continue to market its research and program capabilities to other countries in the East and Southern Region.
3. CTR/Nairobi and the IMPACT Office should work together in developing their workplans in order to capture any synergies.
4. FHI/NC should continue to support strengthening the technical capabilities of CTR/Nairobi in the design, data collection, data analysis and reporting of research and program studies.

5. FHI/NC should evaluate the potential of using IMPACT offices, which currently are located in more than 40 countries, as the home base for launching large-scale Phase2/3 microbicide studies and other types of clinical trials.
6. USAID/DC should consult with the Kenya mission when designing the follow-on project to the current CTR/FHI cooperative agreement in order to ensure that the technical assistance needs of USAID missions for operations research are adequately addressed.

APPENDIX D

REFERENCES

REFERENCES

Family Care International. *Sexual and Reproductive Health Briefing Cards*. New York, 2000.

UNAIDS. *AIDS Epidemic Update*. Geneva, December 2002.

United Nations Population Fund (UNFPA). *State of the World's Population Report*. New York, October 8, 2003.



POPTech

POPULATION TECHNICAL ASSISTANCE PROJECT

1101 Vermont Ave., NW Suite 900 Washington, DC 20005 Phone: (202) 898-9040 Fax: (202) 898-9057 www.poptechproject.com